



**Technological University of the Shannon
Midlands Midwest**

Ollscoil Teicneolaíochta don Sionainn
Lar na Tíre Lar Thiar

Advancing Maxillofacial Prosthetics With Additive Manufacturing Integration: A Comprehensive Examination Of The Irish Landscape.

This research project is submitted in fulfilment of the award of Master of Engineering in Packaging, Innovation and Product Design at the Technological University of the Shannon: Midlands.

Supervisor: Micheal Fitzpatrick

21 April 2024

Plagiarism Declaration

I have read the University's code of practice on plagiarism. I hereby certify this material, which I now submit for assessment on the programme of study leading to the award of Master of Engineering in Packaging, Innovation and Product Design, is entirely my own work and has not been taken from the work of others, only to the extent that such work has cited within the text of work.

Student ID Number: A00303165

Word Count: 15720

Name of Candidate: Kieran Murphy

Signature of Candidate:

Date: 21.04.2024

Acknowledgement

I want to acknowledge the support and guidance of various individuals and institutions who made this dissertation possible.

Firstly, I express my deepest gratitude to my course coordinator, Declan Doran. Their invaluable guidance, encouragement, and expertise throughout this journey have been instrumental in shaping this dissertation. I am grateful for their insightful feedback and unwavering belief in my work.

I would also like to thank my mentor, Micheal Fitzpatrick. Their valuable time, constructive criticism, and willingness to share their knowledge significantly improved the quality of this dissertation.

I sincerely thank my fellow Packaging, Innovation and Product Design researchers for our camaraderie, support, and stimulating discussions. Your collaborative spirit and willingness to share ideas enriched this research experience and significantly contributed to this dissertation's success.

I am incredibly grateful to RS Group for providing the financial support that allowed me to focus on my research without financial constraints.

Lastly, I express my deepest gratitude to my family and friends for their unwavering love, support, and encouragement throughout this entire process. Your patience, understanding, and belief in me kept me motivated during challenging times. A special thank you to my partner, Eamhan, for their patience over the last two years. Their selflessness allowed me to focus on my studies, and I am forever grateful.

All of these individuals contributed to the completion of this dissertation. Thank you.

Abstract	8
1. Introduction:	9
1.1 Background	9
1.2 Research Problem	10
1.3 Research Question	11
1.4 Research Aims	11
1.5 Research Objectives	11
1.6 Research Significance	11
1.7 Research Limitation	12
2. Literature review:	13
2.1 Introduction	13
2.2 Additive Manufacturing Definition	13
2.2.1 Additive Manufacturing Technology: Fused Deposition Modelling (FDM)	13
2.2.2 Additive Manufacturing Technology: Stereolithography (SLA)	15
2.2.3 Additive Manufacturing Technology: Material jetting or PolyJet printing	17
2.2.4 Additive Manufacturing Technology: 3D Scanning	18
2.3 3D printing standards	18
2.4 The Anatomy of the Face, Soft Tissues and Nose	19
2.5 The importance of maxillofacial prosthetics:	20
2.6 Craniofacial and Maxillofacial:	20
2.7 Current Methods:	21
2.8 Polymers in Prosthetics:	22
2.8.2 Polymers in Prosthetics: Silicone poly(dimethylsiloxane)	22
2.8.3 Polymers in Prosthetics: Chlorinated Polyethylene	23
2.8.4 Polymers in Prosthetics: 3D printing polymers	24
2.9 Additive manufacturing proof of concepts:	25
3. Methodology	27
3.1 Introduction:	27
	3

3.2 Research Design:	27
3.2.1 Saunders Research Onion:	27
3.2.2 Chosen approaches:	28
3.2.3 Pragmatism:	29
3.2.4 Inductive approach	30
3.2.5 Mono-method	30
3.2.6 Cross-sectional	30
3.2.7 Qualitative	31
3.3 Limitations	31
3.4 Research Questions	31
3.5 Methods of Analysis	33
3.6 Ethics	33
3.7 Credibility and Reliability	34
4. Findings	35
4.1 Introduction:	35
4.2 Objective 1:	35
4.2.1 Theme 1: Patient Referral	35
4.2.2 Theme 2: Current Maxillofacial Manufacturing Process	36
4.2.3 Appointment 1: Expose Impant	37
4.2.4 Appointment 2: Impression taking	37
4.2.5 Appointment 3: Try-on	38
4.2.6 Appointment 4: Colour matching	38
4.2.7 Appointment 5: Final Fit	39
4.2.8 Theme 3: Retention Methods	42
4.3 Objective 2	42
4.3.1 Theme Four: Maintenance and Aftercare	42
4.3.2 Theme Five: Education	43
4.4 Objective 3	44
4.4.1 Theme Six: 3D Printed Surgical Aids	45

4.5 Review of Findings	45
5. Discussion	46
5.1 Introduction	46
5.2 Objective 1	46
5.2.1 Theme 1: Manufacturing methods	46
5.2.2 Improved Process Map with 3D Printing Integration	47
5.2.3 Model to Print	48
5.2.4 Meshmix and CAD	48
5.2.5 Scanning	49
5.2.6 Slicing	50
5.2.7 Printing	51
5.2.8 Pugh Analysis	54
5.2.8 Process map	56
5.3 Objective 2	59
5.3.1 Theme Four: Maintenance and Aftercare	59
5.3.2 Theme Five: Education	60
5.3.3 Resources - Failure Mode and Effects Analysis	60
5.4 Objective Three:	63
5.4.1 Theme Six: 3D Printed Surgical Aids	63
5.5 Discussion Summary	64
5.6 Review of discussion:	65
6. Conclusion	66
7. References:	69
Appendices	76
Appendix A:	76
Appendix B	78
Appendix C	80

List of Tables and Figures:

Figure 1. Fused Deposition Modelling (Powell et al., 2020).

Figure 2. Stereolithography (Powell et al., 2020).

Figure 3. This is a frontal view of the skull showing the tumour in blue (Mallon et al., 2023).

Figure 4. PolyJet printing (Powell et al., 2020).

Figure 5. Photo of low-fidelity prototypes for interview participants.

Figure 6. Model slicing for optimal Z layers.

Figure 7. TPU Printed prosthetic noses.

Figure 8. PUGH Analysis

Figure 9. New proposed process map with 3D printing integration.

Figure 10. FMEA results

Abbreviations:

3D	Three Dimensional
ABS	Acrylonitrile Butadiene Styrene
CAD	Computer-aided Drawing
CPE	Chlorinated Polyethylene
CT	Computed Tomography
FDA	Food and Drug Administration
FDM	Fused Deposition Modelling
HA	Hydroxyl Apatite
IPA	Isopropyl
MRI	Magnetic Resonance Imaging
NSAI	National Standards Authority of Ireland
PCL	Polycaprolactone
PDMS	Poly(dimethylsiloxane)
PEG	Polyethene Glycol
PLA	Polylactic Acid
PP	Polypropylene
SLA	Stereolithography
SMAS	Superficial Musculoaponeurotic System

Abstract

This study explores the potential of additive manufacturing (3D printing) to improve maxillofacial prosthetics in Ireland. A comprehensive literature review analysed various 3D printing technologies (FDM, SLA, PolyJet) and their applications in facial reconstruction. The review highlights the advantages of additive manufacturing, including customisation, enhanced fit, and the ability to create complex designs. However, limitations, such as the material properties of current 3D printing filaments, may only partially match the aesthetics and durability of traditional prosthetics. A qualitative thematic analysis was conducted using interviews with medical, education and innovation experts. Thematic analysis revealed limitations in the current referral system, a time-consuming manual manufacturing process, and limited training opportunities in maxillofacial prosthetics. While 3D printing is already used for surgical planning aids, the technology is not yet integrated into prosthetic production. However, participants expressed interest in its potential for applications in surgical simulation. These findings suggest that 3D printing has the potential to revolutionise maxillofacial prosthetics in Ireland, but challenges exist regarding education, traditional workflows, and awareness within the healthcare system.

1. Introduction:

Maxillofacial prosthetics serve more than one purpose. They primarily act to reconstruct the face, aid in rehabilitation procedures, enhance speech and protect the affected area from the elements. Prosthetics also play a large part in patient survival and quality of life when reconstructive surgery is no longer an option. Maxillofacial prosthetics allow patients to resume a normal lifestyle as no other body part can reveal emotions and character like the face. However, multidisciplinary teams are needed to manage the development process, from direct patient care to the artisanal manufacturing process. Traditional maxillofacial prosthetics are often time-consuming to produce and difficult to train new practitioners. A growing body of academic work surrounds integrating digital manufacturing tools into prosthetic development. Additive manufacturing or 3D printing has been successfully integrated into several parts of the biomedical, dental and medical device industries. Additive manufacturing allows for highly customisable parts and low-production runs, making it an ideal addition to improve the speed and accuracy of maxillofacial prosthetics. This chapter will begin by discussing this study's background and context, followed by the research problem, research aims, objectives, the significance of this study, and, finally, the limitations.

1.1 Background

The birth of maxillofacial prosthetics dates back to the 16th century, with the work of Ambroise Paré, a French military surgeon. Paré documented early producers, including facial epitheses of gold, silver, paper, and linen, held in place by small laces (Destruhaut et al., 2021). The Industrial Revolution led to the advancement of materials such as vulcanite and celluloid, both lightweight and malleable materials ideal for prosthetic making. After WW1, many craniofacial injuries led to the recognition of maxillofacial prosthetic rehabilitation. American sculptor Anna Coleman Ladd pioneered methods with French maxillofacial surgeons to create masks for the many “broken faces” of WW1. Ladd's work later led to the recognition of psychosocial difficulties faced by veterans impacted by a facial defect, which influenced the creation of laws and unions to protect mutilated soldiers (Destruhaut et al., 2021)

Humanity has recognised the importance of facial appearance for centuries. Facial appearance is vital for mental health and can cause serious public health problems. In recent years, the number of facial trauma incidents has increased. The need for maxillofacial prosthetics has risen due to increased traffic accidents, ageing populations, and higher cancer survival rates (Li et al., 2023). However, maxillofacial prosthetics have remained relatively unchanged since the 1970s, with the improvement of medical-grade silicone, particularly polydimethylsiloxane (PDSM), which is still commonly used today (Nyberg et al., 2016). With methods remaining unchanged and the need rising, maxillofacial prosthetics must be produced at a higher rate than ever before, meaning adopting new manufacturing techniques needs to be considered.

Additive manufacturing encapsulates all 3D printing technology and is one of the pillars of Industry 4.0. In recent years, it has been adopted by aerospace, defence, and biomedical industries. Industry 4.0 represents a new digital transformation era that allows manufacturers to optimise their production processes and increase productivity using digital technologies like 3D printing. However, Ireland needs more adoption across all sectors for Industry 4.0 despite the intrinsic known benefits (Ghadimi et al., 2022). Ireland ranks last in the developed world for digital health policies (OECD, 2023). This may suggest a resistance to change, which may affect innovation in maxillofacial departments. This research aims to prove the applications of 3D printing in the prosthetic manufacturing process and demonstrate the cost and time-saving benefits associated with adopting these methods.

1.2 Research Problem

Academic research, to date, has primarily focused on the medical procedures associated with craniofacial surgeries and the methods and materials used in producing traditional prosthetics. Previous research has shown the capabilities of additive manufacturing technologies, such as 3D scanning and SLA printing, for data documentation and the creation of retention methods. Little research has identified how 3D printing can benefit the value chain in maxillofacial departments.

Thus far, the researcher has not found many studies or examples of 3D-printed prosthetics or tooling used in manufacturing maxillofacial prostheses in Ireland. Due to the complexity of

the prosthetics currently manufactured, an entirely printed alternative prosthetic may only be possible with the invention of new printing technology (Li et al., 2023).

1.3 Research Question

How can maxillofacial prosthetics be advanced with additive manufacturing integration? A comprehensive review of the current opportunities for an efficient future state of maxillofacial prosthetics in Ireland.

1.4 Research Aims

This research aims to detail and overview the current maxillofacial manufacturing value chain and create a list of best practices for integrating additive manufacturing in the manufacturing process. Along the way, the researcher will create low-fidelity digital and physical prototypes to support best practices and act as proof of concepts. The primary research will also identify the barriers to additive manufacturing in maxillofacial processes.

1.5 Research Objectives

1. Explore the current maxillofacial manufacturing value chain and identify best practices for speed improvements with additive manufacturing integration.
2. Identify what resources are needed to improve the implementation of additive manufacturing technologies in maxillofacial prosthetic development.
3. To examine whether a lack of knowledge and application use cases are associated barriers to entry with additive manufacturing adoption.

1.6 Research Significance

This study will complement the current body of work on how maxillofacial prosthetics are manufactured and will expand on the procedures by identifying areas where 3D printing can improve speed. This research will be the first to examine 3D printing for maxillofacial

prosthetics in Ireland and aims to identify ways 3D printing and digital technologies can train future practitioners.

1.7 Research Limitation

- Analysing the procedures associated with Maxillofacial, Craniofacial, and Otorhinolaryngology surgery is beyond the scope of this study.
- This research will focus on craniofacial and maxillofacial prostheses (Auricular, ocular, nasal, orbital, and facial soft tissue). It will not focus on orthopaedic prosthetics for limbs or other prosthetics.
- The paper will branch out into other uses for 3D printing in medicine to help build a clear image of medical applications and how they may be integrated into craniofacial and maxillofacial prostheses.
- Reaching the desired number of participants working in a maxillofacial department might be challenging. The interview may need to be extended to other medical practitioners, industry experts or users of a medical service.

2. Literature review:

2.1 Introduction

This chapter will define our core areas of interest in additive manufacturing and maxillofacial prostheses. The two subjects are vast research areas, spanning engineering, material science, and medical specialities. It is important to touch on a large body of research to understand the challenges of integrating 3D printing into maxillofacial prosthetics. To help narrow down research papers, a list of keywords was identified via a preliminary word association search. The literature will explain the technology associated with additive manufacturing, some common materials, the importance of maxillofacial prosthetics, and current methods.

2.2 Additive Manufacturing Definition

Additive manufacturing, more commonly called 3D printing, is the method of creating a three-dimensional object by adding materials together layer by layer. The three-dimensional object is designed digitally using CAD (computer-aided drawing) software. The printing methods vary, and rapid advancements have been seen in recent years. Some of the most common methods involve the extrusion of thermoplastics, the curing of photosensitive resins or the sintering of a powdered material. 3D printing has various applications in medical devices, aerospace, defence and automotive. 3D printing has the potential to revolutionise healthcare by enabling the custom fabrication of medical devices, prosthetics, retention methods, pharmaceutical dosages and bioimplants (Sun et al., 2023). 3D printing can offer many advantages compared to traditional manufacturing methods, such as low-cost production, customisation, one-off parts, teaching aids, and simulation. In recent years, the technology has been utilised in several studies to create patient-specific implants and orthopaedic prostheses tailored to specific needs (Kantaros et al., 2023).

2.2.1 Additive Manufacturing Technology: Fused Deposition Modelling (FDM)

Fused deposition modelling is one of the most common methods of 3D printing due to its ease of use and low cost of entry. FDM printing is an extrusion method, where thermoplastics

are heated to a semi-liquid state and extruded from a nozzle to a build surface. Depending on the kinematics of the 3D printing, the extruder or the build plate moves in the XYZ direction, depositing material onto the previous layer and creating a 3D printed object. FDM typically follows the same process to produce a 3D printed object, starting with CAD design, exporting CAD design to 3D printing file format, slicing of the object to create a tool path or gcode, and execution of gcode to produce a physical 3D printed object (Wickramasinghe et al., 2020).

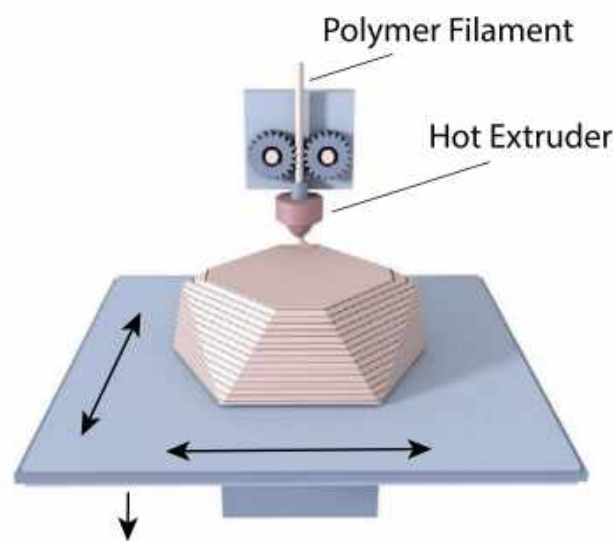


Figure 1. Fused Deposition Modelling (Powell et al., 2020).

FDM printing is made possible due to the thermoplasticity of the polymer filament (Ngo et al., 2023). Polylactic acid (PLA) is commonly used in FDM 3D printing due to its environmentally friendly reputation. PLA is produced through condensation polymerisation of lactic acid derived from carbohydrate sources such as corn and sugar cane (Hong et al., 2012). PLA is a biopolymer and can be composted in the right conditions. An active composter with a controlled temperature of 58 degrees Celsius and a high moisture content can fully break down PLA in 6-12 weeks (Arrieta, 2021). PLA filament also has a low glass transition temperature of about 60 degrees, meaning PLA will begin to become malleable at low temperatures (Suder et al., 2021). Glass transition temperature is when a polymer amorphous material transitions from a rigid, glass-like state to a soft rubbery state (Yu et al., 2020). This is important when programming machines with PLA and other 3D printing filaments. The low glass transition temperature and environmental benefits make PLA an

attractive material for prototyping. However, its low glass transition temperature makes PLA unsuitable for heat-sensitive applications and reduces the friction it can resist during post-processing, such as abrasive sanding.

In medicine, FDM has been successfully used to aid with procedures. It has been used to print cutting aids and guides, printed in bioinert materials like ABS or PP (acrylonitrile butadiene styrene or polypropylene), both materials with optimised slicing profiles for FDM extrusion (Nyberg et al., 2016). Additionally, FDM has been used to produce 3D-printed preoperative planning and training models, allowing for better visualisation (Sayfeddine et al., 2023). While being a cost-effective method of 3D printing, FDM has some known limitations. As a result of its layer-by-layer process, FDM prints have a poor surface quality, which can affect the object's aesthetics (Nyberg et al., 2016). A smooth surface would require additional post-processing. Any abrasive or sanding processing will decrease the dimensional accuracy of the object. The readiness of filament is a limitation, with a relatively small number of thermoplastics on the market. However, recent advancements have been made to improve the availability of composite materials, with increased mechanical properties and higher glass transition temperatures (Wickramasinghe et al., 2020). Increasing the overall stiffness and accuracy of printed parts. While FDM is a cost-effective and accessible 3D printing method, it has limitations regarding mechanical properties, surface quality, material options, and resolution. This makes it an ideal candidate for prototyping and tooling manufacturing but less suitable for detailed-oriented work.

2.2.2 Additive Manufacturing Technology: Stereolithography (SLA)

SLA, or Stereolithography, has been around since 1986 and has become incredibly popular in the automotive industry throughout the late 20th century (Ngo et al., 2018). SLA utilises UV light or an electron beam to react with a monomer solution or resin to form a layer. The UV-active monomers, such as acrylic or epoxy-based, instantly convert to polymer chains after activation. As the resin layer becomes solid through polymerisation, it provides a platform for subsequent layers. After printing, the unreacted resin needs to be removed. SLA parts require several post-processing steps, such as IPA (isopropyl) washing, heating, and photo-curing, to ensure strength. SLA can also be used to print ceramic-polymer composites

or polymer-derived ceramic monomers, which have been studied for osteointegration applications (Ngo et al., 2018) (Eshkalak et al., 2020) (Crafts et al., 2018).

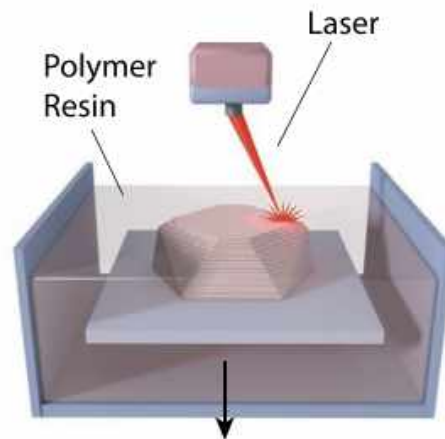


Figure 2. Stereolithography (Powell et al., 2020).

SLA lends itself to similar applications as FDM printing in a medical sense, and depending on the curing method, layer heights can be as small as 10 microns on desktop printers (Eshkalak et al., 2020). This added resolution allows for highly detailed parts. A case study in Northern Ireland proved the benefits of SLA printing in preoperative models. A nasal polyp was scanned, digitally processed and printed to allow for surgical planning, and the polyp was successfully removed. The model benefited the hospital by lowering the resources needed in theatre and staff resources, ultimately leading to a faster turnaround time and reducing hospital bed days (Mallon et al., 2023).

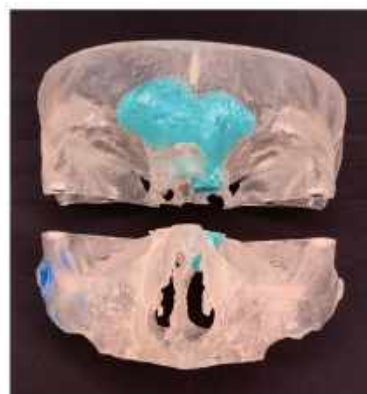


Figure 3. This is a frontal view of the skull showing the tumour in blue (Mallon et al., 2023).

However, SLA is traditionally slow and expensive. Another major limitation is overhanging surfaces of non-trivial sizes. Additional support material is needed to account for overhangs, adding to material costs, printing times, labour for removal and postprocessing times (Karasik et al., 2019). Considering the limitations, SLA is still an attractive method of producing detailed parts and has seen application in maxillofacial surgery.

2.2.3 Additive Manufacturing Technology: Material jetting or PolyJet printing

Material jetting, or poly jetting, is a 3D printing technology using piezoelectric nozzles to extrude a material selectively. Unlike SLA, where the polymer and support structure are suspended in resin, the polymer is extruded onto the build surface (Wei et al., 2022). Typically, this material is a photopolymer; UV light cures each layer as the nozzles pass over. After a layer is deposited and cured, the build surface moves down in the Z direction, and the process can be repeated. It is a versatile technique that can be used for both polymer and ceramic biomaterials, such as polyethylene glycol (PEG), hydroxyl apatite (HA), bioglasses, polycaprolactone (PCL), and polylactic acid (PLA) (Ngo et al., 2018).

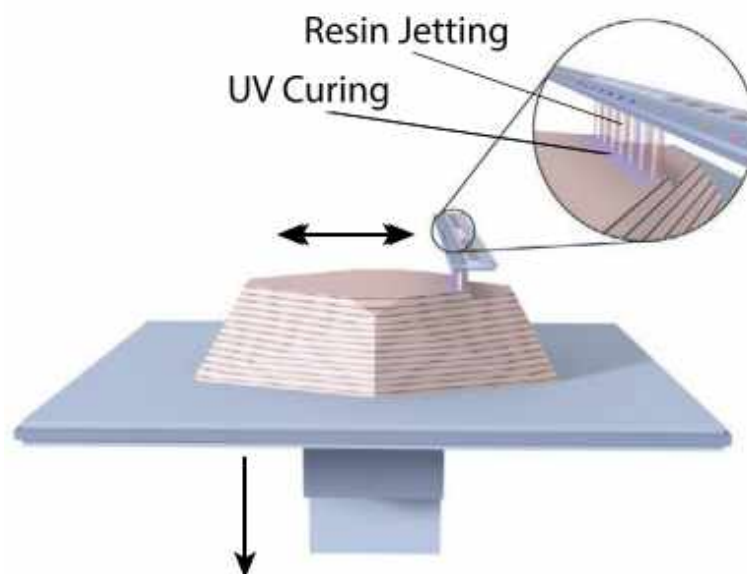


Figure 4. PolyJet printing (Powell et al., 2020).

A key advance of the poly jet is the potential ability to incorporate existing materials, such as silicones. Polyjetting's ability to control the precise deposition of materials with multiple nozzles allows for multiple material extrusions in one pass. The extrusion of multiple raw polymers will lead to tailorable materials (Powell et al., 2020). The ability to print multi-materials allows for coloured anatomical 3D prints. Models have been used to simulate and plan complex craniofacial surgeries (Wei et al., 2022). Material jetting has demonstrated its ability to reproduce delicate details of facial skin microanatomy characteristics, making it a suitable candidate for facial prosthetic digital workflows.

2.2.4 Additive Manufacturing Technology: 3D Scanning

3D Scanning has been incorporated into FDM and SLA printing for some time. The types of technology used to capture and convert the data into 3D meshes have advanced significantly in recent years. Structured light scanners, MRI and CT scans, have been utilised to capture anatomical structures to create digital prototypes and models (Salazar-Gamarra et al., 2022). The goal of 3D scanning is to capture the accurate trueness of an anatomical structure and, more often than not, capture a defect. Various manufacturers distribute cameras/ scanners of varying abilities. However, even an iPhone 11 camera using photogrammetry can produce medically acceptable results. The precision of the scan varied, and caution for mobile photogrammetry methods is advised (Unkovskiy et al., 2022). The paper highlighted the accuracy of different scanners, showing that digitisation of facial defects for digital prototyping and 3D printing manufacturing can be done with a low cost of entry. The study did not explicitly state a specific desired accuracy for 3D scans. However, it emphasised the importance of accuracy in capturing oncological defects and the varying accuracy of different scanning devices.

2.3 3D printing standards

A lack of adopted standards may be a barrier to entry for 3D printing in the Irish Industry. The NSAI produced a document that gives an overview of additive manufacturing standards and current committees working towards future standards to support the industrialisation of the technology. ISO/ TC 261 is a joint venture between ISO and ASTM. The document highlights the role of additive manufacturing in supporting Ireland's green economy, climate

action and industry competitiveness (NSAI, 2021). The standard focuses on a few key areas of the manufacturing process, such as materials, design considerations, test methods, qualification specifications, environment, health, and safety. Companies embracing additive manufacturing as part of their Industry 4.0 transformation can leverage standardisation processes. Standards play a crucial role in the adoption of technology. Standardisation is one of the barriers to executing the technology in Ireland (Ghadimi et al., 2022).

2.4 The Anatomy of the Face, Soft Tissues and Nose

The face is a complex organ comprising various soft tissues, vessels, follicles, cartilage, bone and nervous systems, giving the face and tissue its properties. The superficial musculoaponeurotic system (SMAS) and retaining ligaments support the facial soft tissue and retain the tissue to the bone structure. (Hashiguchi et al., 2022). The facial soft tissue is often broken down into layers for ease of medical training. These layers are arranged in concentric layers, which include the skin, subcutaneous fat, superficial fascia, mimetic muscles, deep facial fascia and the plane containing the facial nerve (Ferneck et al., 2017). Understanding the anatomy of facial soft tissue is crucial for various medical specialities, including when choosing materials for facial prosthetics.

The human nose comprises cartilage and bone, and cartilage primarily forms and shapes the external appearance. Parts of the maxilla bones, palatine bone and nasal bone create the bony framework structure of the nose (Wong et al., 2020). The nose has an extensive blood and vessel supply, which branches from the facial artery. The arteries connected to the nose include the septal branches, angular artery, external nasal artery, dorsal nasal artery, and lateral nasal artery (Proctor and Relman, 2017). The nasal cavity is an essential part of the respiratory system. It plays a role in inhalation and exhalation and serves to warm incoming air. The inferior turbinate and middle turbinate produce sticky mucose, which traps large particulates, preventing them from entering the lungs. A healthy nose will provide 90% of the air and moisture conditioning needed for alveolar conditions. (Sakarya et al., 2020)(Naftali et al., 2005).

2.5 The importance of maxillofacial prosthetics:

No other organ can reveal emotion and feelings like the face, so its alteration highlights an intrinsic need to hide defects and seek restorative care (Salazar-Gamarra et al., 2022). Several different scenarios, such as congenital disabilities, cancer, trauma, infections and diseases, can cause maxillofacial defects. Surgical resection, due to the treatment of cancers and tumours, is another common cause of maxillofacial defects. (Chinta et al., 2022). Morbidity associated with the defects can vary depending on the age and sex of the affected patient. However, common complications are shared. Such complications include speech production disruption of articulation, airflow, nasal reflux during swallowing, and regurgitation of food and water through the nose. Defects in the oral and maxillofacial area can lead to severe appearance deformities and dysfunctions in speaking, chewing, swallowing, and breathing, significantly impacting the patient's quality of life (Sudhakar, 2017). Overall, the morbidity associated with maxillofacial defects highlights the importance of both reconstructive techniques and prosthetic rehabilitation.

In more detail, patients who require prosthetic restoration usually exhibit certain conditions: They may have a significant cranial and maxillofacial defect resulting from facial tumour surgery, trauma, or congenital malformation. The loss of a facial organ, such as the eye, nose, ear, etc may accompany this defect. As a result, the local defective tissues and organs present a very complex anatomical morphology. They may have a primary malignant tumour that easily relapses after treatment. Poor blood flow in the soft tissue bed of cranial and maxillofacial malformations makes surgical repair difficult (Nyberg et al., 2023). Patients' age and time cost pose challenging requirements for surgical repair. When patients exhibit such conditions, facial prostheses can be considered to improve their appearance and facial function.

2.6 Craniofacial and Maxillofacial:

The literature review has highlighted the need to distinguish between craniofacial and maxillofacial. Both terms are closely linked to medical fields of study and are often used interchangeably while referring to head and neck craniofacial surgery as an extension of maxillofacial surgery. Craniofacial refers to the upper facial skeleton and requires a

transcranial approach for access, while maxillofacial involves anatomy below the inferior orbital rim. However, craniofacial surgery is an extension of maxillofacial surgery, utilising techniques such as osteotomies and skeletal repositioning initially developed for maxillofacial problems (Mao et al., 2022).

2.7 Current Methods:

The process of designing and manufacturing maxillofacial prosthetics is lengthy, with maxillofacial rehabilitation being managed by multidisciplinary teams with a broad scope of knowledge. The three main areas of maxillofacial surgery are rehabilitation, reconstructive and regeneration. When all methods are exhausted, reconstruction with a prosthetic is often the last available choice for the patient. Prosthesis dramatically improve a patient's quality of life, from protecting the affected area to enhancing speech (Nyberg et al., 2016).

Current methods utilised involve several different technologies, both digital and analogue; even additive manufacturing tools are incorporated successfully in some markets. Traditionally, the process begins with capturing the defect area with a scanning tool and impression. This data is then used to make informed design decisions. The imaging is typically captured by onsite metrology equipment like a CT machine. The conventional prosthetic creation method involves taking an impression of the patient's affected area using alginate or silicone. The imprint is then used to create a plaster casting and wax model. The wax model is placed into a mold for the loss wax method, and silicone is injected. This process results in the final prosthetic. Further shaping and hand carving are done to reach the desired shape. The last step is the colour-matching process; while several methods are used, it is considered an artisanal process. The end aesthetics are often subjective, which affords a certain amount of trial and error in the colour-matching process (Miechowicz et al., 2020).

In recent years, the addition of computer-aided technology has become increasingly commonplace, with use cases found in surgical planning, design, reconstruction and colour matching. Importantly, its use in design aligns the process closely with the tools commonly used for 3D modelling and other digital fabrication tools. Digital workflows can speed up various stages of the manufacturing process and allow for rapid digital prototyping, where digital workflow output is typically derived from MRI or laser scanners and can produce

accurate mesh files. These mesh files act as a digital impression, where a digital prototype can be designed and exported for 3D printing. A talented technician can turn around a scan to mesh to a physical prototype in several hours. Direct-to-prosthetic 3D printing has its limitations due to the availability of suitable materials (Powell et al., 2020).

2.8 Polymers in Prosthetics:

In the best-case scenario, a perfect material would replicate and replace the missing tissue and have similar biomechanical features. While there is no direct replacement, synthetic materials must satisfy some requirements such as nontoxicity, biological compatibility, mechanical strength and simplicity of handling for manufacturing (Mitra, 2014). Material choices vary depending on the anatomy being replaced, and several factors must be considered. The choice of material depends on the specific facial structure being replaced or reconstructed, the desired appearance and texture of the prosthetic, and the durability and flexibility required for proper function (Powell et al., 2020). Silicone is often preferred for maxillofacial prosthetics due to its lifelike appearance, soft texture, and biocompatibility with the human skin. It can be easily moulded and customised to match the patient's natural features, resulting in a highly realistic and comfortable prosthesis (Mitra, 2014). Silicone elastomers satisfy several factors when picking a material for maxillofacial prosthetics. However, it has been noted that silicone elastomers can have poor tear strength, meaning they can often be damaged during regular use (Lanzara et al., 2022). Prosthetics for the nose are often thin in areas that interface with the face around the eyes and cheekbones. The edges can tear depending on the adhesion method, such as glue. This leads to additional maintenance, with some labs reporting facial prosthetic maintenance being needed every 1-2 years (Li et al., 2023). While the complex anatomy of the various features of the face cannot be replicated with synthetic materials, some of the essential characteristics can be met. The search for the ideal replacement material remains the subject of many research papers.

2.8.2 Polymers in Prosthetics: Silicone poly(dimethylsiloxane)

PDMS, or poly(dimethylsiloxane), is a commonly used material in the fabrication of maxillofacial prosthetics. PDMS was first introduced into prosthetics in the 1970s (Miechowicz et al., 2021). It is typically used to create custom-made devices to replace

missing tissue and cover underlying tissue. PDMS prostheses are traditionally made through a workflow that involves casting duplicates using moulds or, more recently, 3D-printing negative molds for casting the final PDMS prosthesis (Ngo et al., 2018). PDMS has excellent biocompatibility, as it is chemically inert, making it suitable for contact with the skin and oral tissues. This reduces the risk of allergic reactions or skin irritation in maxillofacial prosthetics patients. PDMS is resistant to moisture and can withstand exposure to saliva and other fluids commonly found in the oral cavity, enhancing the longevity of the prosthetic (Cruz et al., 2020). Studies have shown that acidic and alkaline perspiration can be absorbed into the silicone and weakened. This increases the hardness of the silicone, making it subjectable to damage. Meanwhile, depending on its composition, sebum and other secretions have varying results on the silicone. (Al-Dharrabet al., 2013). PDMS can mimic facial tissue softness and flexibility, making it easier to wear than substitute materials. However, PDMS elastomers are significantly more rigid than facial skin, with stiffness up to 6.4 times higher, which can lead to wearer fatigue (Beatty et al., 2023).

PDMS is favoured among prosthetists due to its ease of use in manufacturing. Silicone can be easily cross-linked (a bond that links one polymer with another) with a catalyst to begin a condensation or addition polymerisation. Condensation polymerisation allows for room-temperature vulcanisation, and addition polymerisation allows for high-temperature vulcanisation, allowing the material to be molded, replicating the missing facial feature (Cruz et al., 2020). It can be shaped using different methods and is available in various composites, and additives can enhance its mechanical properties to improve the lifetime of the prosthetic. PDMS may not have the same level of strength and durability in its basic form as other materials used in maxillofacial prosthetics, such as chlorinated polyethylene or other elastomers. This can limit the overall longevity and durability of the prosthetic but also may affect its ability to bridge significant defects.

2.8.3 Polymers in Prosthetics: Chlorinated Polyethylene

Chlorinated Polyethylene, or CPE, is a thermoplastic elastomer commonly used in industrial applications. It was first suggested as a suitable prosthetic material at the National Institute of Dental Research Conference in 1973, where research began to find new formulations of CPE for maxillofacial prostheses (Powell et al., 2022). CPE is typically supplied in sheets and requires heated moulds to shape. The elastomer can be intrinsically coloured during the manufacturing stage or extrinsically stained during the moulding stage. CPE is an inert

elastomer. It is considered less irritating to mucosa than silicone and less toxic during crosslinking for high and low-temperature vulcanisation (Mitra, 2014). Unlike silicone, which tends to become harder due to crosslinking over time, CPE undergoes chain scission reactions during degradation, meaning the polymer will become softer with use (Cruz et al., 2020). CPE does offer several advantages for prosthetics. It is easier to repair and recondition for minor corrections or general maintenance. CPE has superior tear strength and surface wettability when compared to silicone. It is highly versatile and can be used with various adhesives.

Additionally, it is resistant to fungus growth, making it a reliable and safe option for various applications. (Powell et al., 2020). CPE is a suitable replacement material due to its availability and where the cost of the prosthetic is a concern (Mitra, 2014). During a clinical trial, patients who were unfamiliar with prostheses were blind fitted with a CPE prosthetic and a PDMS prosthetic; the results showed the patients had no preference between the two materials; it is worth noting that patients who previously wore a PDMS prosthetic preferred the fit and comfort of the silicone over CPE. (Kiat-amnuay et al., 2010)

2.8.4 Polymers in Prosthetics: 3D printing polymers

Packing silicone into gypsum moulds and processing it traditionally takes up much time and necessitates the presence of both the patient and the treating clinician. The discussed literature highlighted 3D printing uses in medicine, which included aids for prosthetics. However, prosthetic printing is still in development, and the biocompatibility of 3D printing is still undetermined. While there are antibacterial filaments on the market, the layer lines can potentially harbour bacteria (Zuniga, 2018). The favoured prosthetic materials are PDMS and CPE, which are not readily available for FDM printing. Total digital workflows have been trialled, and soft tissue-like direct 3D printed parts have been produced from a Stratasys J750 polyjet printer (Nuseir et al., 2018). However, the biocompatibility of the direct print was not discussed, and the printed object was treated with silicone relining to aid with staining and adhesion. This method removed the need for gypsum moulds but added additional 3D printing post-processing steps. Formlabs has released their own formulated silicone (Silicone 40A) material for SLA printers. Currently, colour options are limited, but SLA-printed prosthetics have future potential (Formlabs, 2023).

Additionally, 3D printing can replicate the hardness needed for the substructures. Copolyester is an FDA-approved filament suitable for medical applications. It should not be confused with Chlorinated Polyethylene, as they share the same CPE abbreviation. It is both hard and chemical resistant, making it a suitable replacement substructure compared to traditional materials like acrylic. Since copolyester is widely available in filament form, it has highly optimised printing profiles for FDM printing, meaning the benefits of copolyester can be integrated into the current manufacturing process with a low financial and knowledge barrier to entry.

2.9 Additive manufacturing proof of concepts:

Prosthetics are a one-off customer solution involving multifunctional teams of end-care practitioners and prosthetic technicians. Several proofs of concept have been trialled in various maxillofacial labs and research centres across the globe. A prosthetic-attached eyewear was devised for a cancer patient who can no longer receive further rehabilitation surgery (Ciocca et al., 2023). The prosthetic was designed using a digital workflow and proved faster than traditional methods. It utilised overlapped CT bone and laser skin scans to determine the position of the prosthetic, creating a digital prototype. Additive manufacturing was used for the retention methods, as the substructure was printed in titanium, and the prosthetic was printed using polyjet technology. The limitations of this method are that polyjet and titanium parts are prohibitively expensive and unobtainable to most hospitals. Extrinsic colouring was still needed, and the prosthetic was permanently attached to the eyewear. The research further proved that additive manufacturing could be used to create prosthetic retention methods. The limitation advantage of printing techniques is the total time for prosthesis production, which in one study took up to 98 hours, with the most time spent printing. (Miechowicz et al., 2020).

To date, research in maxillofacial 3D printed prosthetics is lacking. The author made significant attempts to find as much relevant research as possible. Printing prosthetics has apparent benefits and has shown promise in maxillofacial departments in aiding the tooling and manufacturing of ocular prosthetics by mirroring an ocular feature to cover a defect (Sherwood et al., 2020). This method aids with the try-on stage of prosthetic development

and allows for quicker feedback stages. The limitation is that the prosthetic must still be manufactured using traditional methods after the try-on. Alternatively, 3D printable nasal prosthetics have been relined with medical-grade silicone, providing a body-safe method. This allows for the design and try-on stage of development to be done digitally (Cicco et al., 2023). However, the retention methods of this study proved complex, relying on an eyewear retention method with an expensive titanium-printed bracket. The closest method is an experimental direct-to-silicone printing method. Where a prosthetic can be designed digitally, printed, and worn by a patient, this method proves promising. However, extensive post-processing is required to remove the layer lines from the printing process (Nuseir et al., 2019). Additionally, the silicone prosthetic needs to be relined and extrinsically coloured due to the monotone printing process. These methods prove promising and offer several learnings on integrating additive manufacturing technologies into the maxillofacial process.

3. Methodology

3.1 Introduction:

The research methodology chapter will outline the key research strategies most suitable for achieving this study's aims and objectives. Scientific research must be method-driven to develop and test theories. Results can not be driven by intuition alone (Flick, 2015). A clearly defined and structured methodology is essential to systematically solving the research problem. To help identify the correct processes, the author will follow the Saunders research methodology, more commonly called the research onion (Saunders et al., 2012). The Saunders research onion framework allows the author to categorise methods in pursuit of data collection and data analysis. Once the appropriate framework has been set out with the help of the research onion, the methodology will outline the procedure undertaken for the primary data collection. This will consist of a detailed analysis of a qualitative series of interviews, which will be looked at through a thematic lens. The interviews directly targeted the industry's manufacturing methods for maxillofacial prosthetics. The criteria for participation selection will be outlined, along with the potential limitations of the research methods selected. Finally, any ethical concerns with the research will be discussed and mitigated.

3.2 Research Design:

3.2.1 Saunders Research Onion:

The research onion, developed by Mark Saunders, Philip Lewis and Adrian Thornhill, is a comprehensive framework designed to lead researchers through the different stages of the research process. The research onion is often depicted as consisting of several layers, each layer adding depth and complexity. The onion metaphorically represents the intricacy of research design while providing a structured approach for planning and executing research. Ensuring the researchers do not exclude essential elements and follow the best practices to produce high-quality, trustworthy results.

At its exterior, the onion consists of research philosophy reflecting the researcher's fundamental beliefs about reality, knowledge and values. This foundation influences

subsequent decisions regarding research approach, strategy, time horizons, data collection techniques, and data analysis methods. Moving inward from the exterior, the researchers progress through various layers, each building upon the previous one:

1. **Research philosophy:** This layer explores the researcher's fundamental beliefs about reality, sources of knowledge or facts, and values, influencing their approach to research and overall worldview.
2. **Research Approach:** Next, researchers determine their overarching approach to inquiry, whether deductive or inductive, which guides how hypotheses or research questions are formulated and collect evidence to address them.
3. **Research Strategy:** Researchers then select specific methodologies and techniques for data collection and analysis, such as experiments, surveys, interviews, or case studies, tailored to their research objectives and constraints.
4. **Choices:** Based on the above, a decision needs to be made about the type of analysis the researcher will use, whether quantitative, qualitative, or mixed methods.
5. **Time Horizons:** This layer involves decisions about the temporal scope of the study, whether it is a cross-sectional snapshot or a longitudinal examination over time, influencing the design and interpretation of findings.
6. **Techniques and procedures:** Researchers choose appropriate tools and methods to gather empirical primary/ secondary data from participants or sources, considering factors like feasibility, reliability, and validity.

Researchers ensure coherence between their philosophical underpinnings, research goals, and methodological choices, leading to rigorous and credible research outcomes by systematically navigating through these layers (Saunders et al., 2009).

3.2.2 Chosen approaches:

Research Onion Layers	Chosen Approaches
Research Philosophy	Pragmatism
Research Approach	Inductive
Research Strategy	Interviews

Choices	Mono-method
Time Horizons	Cross-sectional
Techniques and procedures	Qualitative

The above approaches were chosen to address the research aims and objectives best. The following reasons justify the decisions.

3.2.3 Pragmatism:

Pragmatism is a philosophical approach that emphasises practical consequences and real-world outcomes. It suggests that the truth of an idea is determined by its practical effects and usefulness in achieving desired goals (Kaushik and Walsh, 2019). Pragmatism was applied in several ways:

1. Focus on practical outcomes: Pragmatism encourages focusing on practical solutions and outcomes rather than abstract theoretical concerns. In this instance, the research prioritised the practical use of 3D printing in prosthetic design, testing various tools and techniques.
2. Emphasis on experimentation and innovation: Pragmatism values experimentation and innovation to solve practical problems. The research will test innovative manufacturing methods against the currently established methods.
3. Consideration of diverse perspectives: Pragmatism encourages considering a variety of perspectives and approaches to problem-solving. The research will examine the various perspectives of stakeholders and how short-term gains can be made.
4. Evaluation of effectiveness: Pragmatism emphasises evaluating ideas and methods based on their effectiveness in achieving desired outcomes. Effectiveness can be rated using various techniques, such as FMEA analysis (Failure mode and effects analysis).

A pragmatic philosophical framework focuses on practical solutions, experimentation, and effectiveness in maxillofacial prosthetic design.

3.2.4 Inductive approach

An inductive reasoning approach best suits this research, as the author had not established a hypothesis before the work began. Unlike deductive reasoning, which starts with a hypothesis and seeks to test it through empirical observation, inductive reasoning starts with observations. It aims to derive general principles or theories from them. This approach will allow the author to develop observations and theories based on the secondary research and the primary interviews with industry experts. Inductive research begins with specific observations or data and then works towards developing broader generalisations or theories (Ritchie and Lewis, 2003). It allows for exploring new or emerging areas of study where existing theories or frameworks may be lacking.

3.2.5 Mono-method

A mono-method approach was taken to overcome the research project's limitations. The sample size for experts working in the maxillofacial industry in Ireland is small, and direct interviews with patients were removed due to ethical concerns. The mono-method approach allowed the researcher to interview experts across industry sectors and other stakeholders. It also allowed for flexibility in research design, allowing the researcher to tailor methods to the specific needs of the research question.

3.2.6 Cross-sectional

The cross-sectional method will be used since the researcher is interested in the current methods. This method allows for investigations into recent innovations and assesses their feasibility, efficacy and potential impact on manufacturing methods. The research's number one objective is to identify areas at which speed improvements can be made with 3D printing, utilising currently available technology. This means that a short-term study is ideal for identifying current challenges. A longitudinal method would benefit future research as 3D printing technology progresses rapidly.

3.2.7 Qualitative

The qualitative approach was chosen because it allows for flexible and iterative design, allowing researchers to adapt their methods and techniques as they gather data and uncover new insights. Since the interviews are vital data points for the research, a qualitative approach allows the author to explore the opinions and beliefs of professionals in their field.

3.3 Limitations

The EPO has reported that 3D printing technology grew eight times faster than any other technology field between 2013 and 2020 (EPO, 2023). With the number of patients rising and startup companies joining the sector, 3D printing technology could experience rapid changes in the coming years. This means that innovations could arise after this research has been published. This poses a challenge in keeping the literature review up to date. The research onion is a valuable tool for designing a study, but it has limitations. An inductive approach relies on specific observations. The conclusions drawn through inductive reasoning are not guaranteed to be universally applicable and may require further testing and refinement in future studies. Qualitative research can be susceptible to biases, as it involves interpreting collected data, meaning the researcher's beliefs may shape how data is collected.

3.4 Research Questions

This study establishes the current manufacturing methods of maxillofacial prosthetics in Ireland and how improvements can be made with the help of additive manufacturing technologies. The objectives of the study are detailed below:

1. Explore the current maxillofacial manufacturing value chain and identify best practices for speed improvements with additive manufacturing integration.
2. Identify what resources are needed to improve the implementation of additive manufacturing technologies in maxillofacial prosthetic development.
3. To examine whether a lack of knowledge and application use cases are associated barriers to entry with additive manufacturing adoption.

The literature review was carried out using a keyword search. It identified papers contributing to three key areas: additive manufacturing, maxillofacial and value chains. Further words were used to narrow down papers and identify connections between the three key areas.

This gave the researcher a grounded knowledge of established methods of manufacturing maxillofacial prosthetics around the globe, as well as the key stakeholders involved. The literature review helped design a semi-structured interview based on fourteen questions to help address three key themes. An additional thirteen questions were prepared should the participant lead the interview down a particular area of expertise. The researcher has also supplied physical 3D-printed prototypes to the participants. A general conversation was had around their impressions of the low-fidelity prototypes and how they were manufactured. The interviews will be conducted with experts in medicine, education, and the additive manufacturing industry. Additional photos are in Appendix C.



Figure 5. Photo of low-fidelity prototypes for interview participants.

The following participants were approached for interview:

- Senor consultant in maxillofacial surgery.
- Senor prosthetic technician specialising in prosthodontics and maxillofacial prosthetics.
- Educators in innovative medicine.
- Senor simulation technicians in surgical training.
- Senor management in surgical simulation.
- Innovation and Design Consultants in the HSE.

3.5 Methods of Analysis

Thematic analysis is a popular qualitative research method and can be applied to various research questions and epistemologies. It can effectively identify, analyse, organise, describe, and report themes within a data set (Braun and Clarke, 2006). Braun and Clarke also emphasised the importance of inductive reasoning in the thematic analysis framework, allowing the themes to emerge from the data. The advantage of the framework is flexibility, which can be modified to suit the needs of the study. In an interview setting, data analysis and data collection can happen concurrently, meaning the data analysis may not be distinguishable from the data (Thorne, 2000). While many authors have set out a phased linear method of thematic analysis, it is essential to remember that it is an iterative process that develops over time and reflection.

3.6 Ethics

Patient safety and welfare must always take precedence over the advancement of scientific knowledge or the researcher's interest, as Beecher (1966) emphasised. Furthermore, Beecher stressed the critical importance of informed consent, arguing that participants must be fully informed about the nature of the study and their right to withdraw. When designing research, the following ethical principles need to be considered.

1. Informed consent: ensuring the participants are correctly notified of the research's purpose.

2. Confidentiality and Anonymity: Respect the confidentiality of participants by safeguarding their identities and any sensitive information shared during the interview.
3. Respect for Autonomy: Recognise and respect participants' autonomy by allowing them to freely express their views and opinions without coercion or undue influence.
4. Minimisation of Harm: Take measures to minimise potential harm or discomfort to participants during the interview process. Be mindful of sensitive topics and refrain from asking intrusive or inappropriate questions.
5. Transparency and Integrity: Maintain transparency and integrity throughout the interview process by providing accurate information about the research objectives, The role of the interviewer, and how the interview data will be used and analysed. Report the findings accurately and with integrity.

Following the above best practices, the author has set procedures to ensure participant safety and well-being. The author has prepared an information sheet detailing the research questions, the participant's rights, and why the participants were selected for an interview. This also details the relevant contact information for the researcher and supervisor should the participant have any concerns. After reviewing the information sheet, the participants were asked to read and sign the consent form, a copy of which can be found in Appendix X.

The author has also consulted the TUS code of ethics and ensured that university standards and procedures are followed. Due to the nature of the research question, ethics has underpinned every aspect of the research.

3.7 Credibility and Reliability

The research onion framework, when followed, allows for credible results, as a robust methodology will stand the rigour of peer-reviewed analysis. The methodology discussed has considered concerns about the credibility and reliability of scientific research. Ioannidis (2005) emphasised the importance of transparent reporting and adherence to sound scientific practices in minimising biases and enhancing the validity of research findings. The participants for the study were carefully chosen based on their experience and knowledge of medicine, education, and 3D printing.

4. Findings

4.1 Introduction:

The methodology chapter has outlined the qualitative technique and the framework used in the research. The literature review has analysed relevant literature from the world's top minds in medicine, prosthetic design, maxillofacial/craniofacial prosthetics, 3D printing, scanning and imaging. From the literature, fourteen questions were prepared for an open-ended interview. Six key experts working within medicine, education, innovation, and 3D printing with first-hand experience in manufacturing maxillofacial prosthetics or involved in a stakeholder capacity were interviewed to explore their beliefs, knowledge, and suggestions. The interviews varied between 30 and 60 minutes, with two participants offering an hour-long tour of their education facilities and maxillofacial laboratory. The interviews were conducted flexibly. In-person interviews were preferred, but online and phone interviews accommodated schedule conflicts. A qualitative thematic analysis approach was used to analyse the interview findings, which revealed six themes that address the objectives of this study.

4.2 Objective 1:

The findings from the interviews revealed three key themes related to objective one, which set out to learn the currently used methods of producing maxillofacial prosthetics in Ireland and the improvements additive manufacturing could bring.

4.2.1 Theme 1: Patient Referral

Each patient will have a different experience on their treatment journey, with procedures to rehabilitate and reconstruct facial features being offered across the Republic of Ireland. This means that patients arrive from two avenues: those treated within the hospital with the maxillofacial prosthetic service and those referred from surgeries around the country once they have finished their cancer or trauma journey.

"Patients are referred from two avenues. ENT surgeons or maxillofacial surgeons. Who perform procedures to remove an ear, a nose, or an eye due to cancer or, for example, treat a patient after a road traffic accident" Participant 2.

According to Participant 5, the referral process can sometimes be accidental. The knowledge of a maxillofacial prosthetic service is not well known within the Irish healthcare system. Patients were often left in a difficult situation, having to seek their own solutions, in some cases being referred to the UK for maxillofacial prosthetic services.

"Some patients being treated in the West had to find a solution based on their own intuition and instinct. Since the surgery did not happen in the hospital where the maxillofacial prosthetic service is located, some surgeons were sending their patients to the UK for a solution, and some of the staff weren't aware" (Participant 5).

Participant 5, an innovation designer within the HSE, has considerable experience interviewing patients about their pain points while undergoing treatment for maxillofacial cancers. They found that the patient's treatment journey can be several years due to operations and radiotherapy. During treatment, patients are left without a solution while they heal, and bone density increases to allow for implants. Often, a nurse or the patient will apply a bandage over the affected area in the interim. Participant 5 interviewed a patient with implant complications that resulted in 5 years without a permanent solution.

4.2.2 Theme 2: Current Maxillofacial Manufacturing Process

The prosthetic technician detailed the manufacturing methods used to create a maxillofacial prosthetic. Using a nose as an example, the participant details the manufacturing process for creating an end-use prosthetic, blocking out each appointment with the patient, time requirements and manufacturing process used to create the end-use, medical-grade silicone prosthetic.

4.2.3 Appointment 1: Expose Implant

A maxillofacial prosthetic is the last step in a treatment journey. At this stage, the patient has received all the care they need to treat their injury, cancer, or congenital disease. Typically, when they arrive for a prosthetic, the patient has received their titanium implants, which would have been given time to heal. During the minimum three-month healing process for the implant, the surrounding tissue will begin to grow over it. This needs to be trimmed before impressions can be taken.

"The patient would've had surgery, and implants would've been in place. So now we're three months on where we're getting down to the end of the journey with them. The area of the implant would be numb, and the implants would be exposed. A healing abutment is installed, and the patient is sent home to heal for a week"

Participant 1.

A healing abutment is a small, screw-shaped piece, described as “a mushroom top”, typically made of titanium that is placed on top of an implant after it has been surgically inserted into the maxilla. The healing abutment acts as a cover for the implant. This is important for preventing infection and promoting osseointegration, the process by which the implant fuses with the jawbone. The healing abutment remains in place for several weeks or months. Additionally, the healing abutment allows the technician to measure the abutment needed for the finished prosthetic accurately, i.e., setting abutment and magnet depth in the prosthetic for a perfect fit on the face.

4.2.4 Appointment 2: Impression taking

During the second appointment, an impression of the face is taken. This impression is taken with a clay or alginate material. Pressed into the affected area, it creates a tooling for the technician to design the prosthetic.

"We remove the healing abutments and put on the permanent abutments with a cap. This allows for impression-taking, which gives me a basic start on the prosthetic"

Participant 1.

Taking impressions of the face is difficult due to the patient's position, sitting back in their chair. The skin and tissue will flex and move, accompanied by the moderate pressure applied to the face, leading to a degree of distortion that the technicians must consider when designing the mould. Impression-taking is often done historically over the healing period, and each impression may differ slightly.

"Sometimes impressions will take 2 or 3 attempts. Maybe the area was swollen, or the patient made a face" Participant 5.

4.2.5 Appointment 3: Try-on

The technician has now had time to work on a wax nose for the try-on appointment. Using sample noses and photos supplied by the patients helps the technician shape a wax nose that will eventually be used in the lost wax method.

"The next appointment would be to try on a nose, something somebody might have printed for me. See, did the patient like it? Did it sit in the middle of their face? And if the patient is happy with it, I'd call this the try-on appointment."

The wax is a positive form and can be shaped in real-time in front of the patient. If it's too small, the technician may have to cast another wax model, which can further delay the process. Due to scheduling constraints, when the patient is done consulting on their prosthetic, the patient may not receive a follow-up appointment for several weeks, further increasing the time without a permanent solution.

"The patient invariably thinks it looks different, as this could be the first time the patient sees themselves with a nose in months. It can seem strange to them. They often request lots of changes, too big, too small, it goes through a lot of tweaking."

4.2.6 Appointment 4: Colour matching

The next appointment can be lengthy, involving the patient being present for the colour-matching and mixing process.

"The next appointment would be a colouring appointment, where you mix silicon to the same colour as the patient and pack a mould of the shape we've just decided on."

The materials used for the prosthetics are manufactured by Technovent, Elastomer 42. E-42 is a low-viscosity, platinum-based, clear medical-grade silicone with a mixing ratio of 10 parts silicone to 1 part platinum catalyst. E-42 has a durometer reading of Shore A-40 when set, making it a soft silicone. After the interview, a tour of the maxillofacial lab was given, where the materials and moulds could be observed. Using the ratio above, the technician intrinsically shades the silicone; sometimes, a thixotropic agent is used to thin (increase viscosity) the material. Next, the mould can be packed; it is recommended that the mould is overfilled by 10% to ensure the mould is packed sufficiently; this also helps with degassing the silicone. Various methods can be used for curing; the manufacturer suggests 2 hours in a 100°C oven or bench cure overnight at room temperature for 6-8 hours.

Colour matching is subjectively done by eye; digital tools are available, but the participants feel the tools are difficult to use and often yield negative results. It is much easier and faster to match the skin tone by eye. Red flocking powder is added to the silicone during mixing to improve colour matching. This mimics capillaries and adds a degree of realism.

"Through that effect (red flocking), the prosthetics achieve versatility across ranges of skin types" Participant 5.

4.2.7 Appointment 5: Final Fit

This visit is the shortest part of the journey. If the patient and technician are happy with the final fit, they can leave with the prosthetic that day. A patient would spend at least an hour with Participant 1 on each visit. On average, the timeline for the above would be 4 to 6 months. The participant gave an example of a patient who received their first impression in August 2023 and fitting with a final colour-matched prosthetic before Christmas 2023. Participant 1 said this visit could only take 5 minutes. The outlined manufacturing methods

will be explored in the discussion section, and areas where additive manufacturing could help, will be prototyped and compared to established procedures for validation. The process map can be seen in Figure 6.

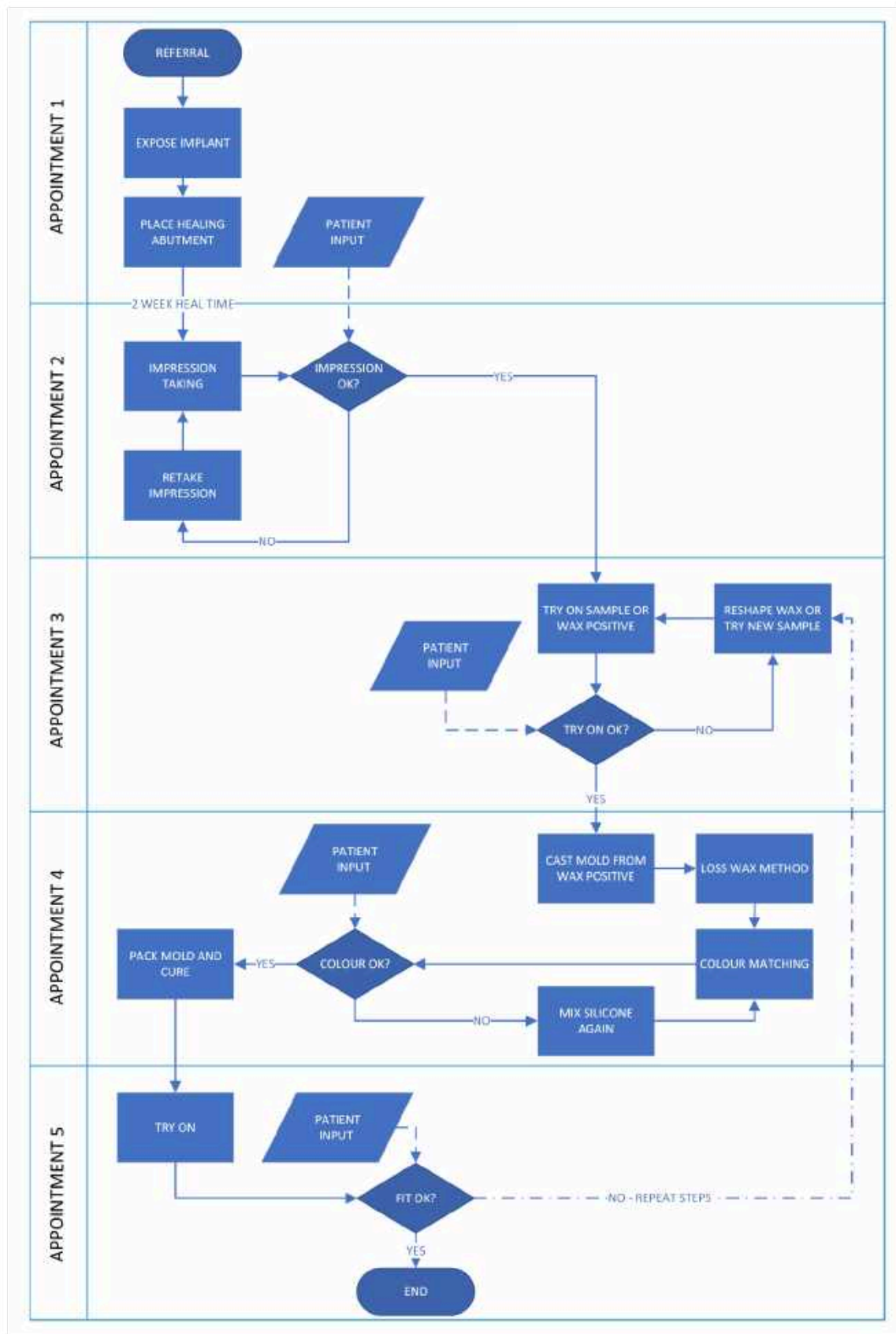


Figure 6. Process map from interviews.

4.2.8 Theme 3: Retention Methods

Retaining the prosthetic in the body is typically done via an implant. The brånemark system by Nobel Biocare is a popular range of dental implants used for retaining nasal, orbital, and aural prosthetics, and it is currently in use in Ireland. The success rates of implants vary depending on treatment factors. During radiotherapy, bone density decreases, meaning successful osseointegration of an implant may take several attempts.

"Sometimes, if patients have radiation treatment, the healing process (osseointegration) isn't as good, and they might fall out at some stage. Let's say generally. There is probably a retention rate of about 80% plus" Participant 2.

"Often, patients have multiple implants put in, and sometimes, they might only need one or two to retain the prosthesis. For example, the prosthetic might only need one implant to retain. The additional implant can be kept as a reserve and exposed if it falls out" Participant 2.

Should additional retention be needed, medical glue can be used to attach the prosthetic's feathered edge to the face. This is sometimes an option should osseointegration fail.

4.3 Objective 2

The interviews' findings highlighted two major themes to address: Identify what resources are needed to improve the implementation of additive manufacturing technologies in maxillofacial prosthetic development.

4.3.1 Theme Four: Maintenance and Aftercare

The literature review highlighted the need for regular maintenance and replacement of the prosthetics on average every 2 years. The participants state that this is only the beginning of the journey and that the patient will have follow-up visits for life. The prosthetic is subject to discolouration and fit problems due to sunlight exposure and facial changes due to ageing and

weight loss. Weight gain in the face can have a positive effect; since the silicone has a Shore A hardness of 40, it is very flexible, and the patient can "grow into their prosthetic", Participant 1 states. The final products are life-like, and both participants agreed that the patients were delighted with the results. The silicone does a great job of replicating human anatomy.

"Eventually, it gets bleached and turns white due to sun exposure. This means that a patient will have follow-ups for life. The discolouration varies depending on the person, but typically 2 to 3 years before a replacement is needed." "I advise patients to sun factor protection on the nose to slow bleaching." (Participant 1)

"It would be difficult to bond something onto the silicone, and there is not much material anyway, so it is just easier to make a new one" (Participant 5)

Foreign bodies can cause soft tissue reactions, and the patients require additional aftercare of the implant areas. Often, it involves "trimming" the excess tissue growth around the implants. Participant 2 states that nearly all patients will require skin maintenance in their lifetime.

"Sometimes, the patient will need skin maintenance around the prosthetic and implants. They can be areas of infection, or the patient may experience hyperplastic tissue growth around the implants because the silicone sits over them. The skin gets inflamed if they wear the prosthetic 24/7" (Participant 2).

With the number of patients requiring maxillofacial prosthetics rising, the department could expect 5 or 20 new patients a year, putting further pressure on the system.

4.3.2 Theme Five: Education

Getting trained in making facial prosthetics in Ireland appears limited. Although a dental technician course lays the groundwork, advanced training seems scarce. One interviewee mentioned a Master's program at King's College London as the only known option for specializing in this field.

"You must take a dental technician course first and learn about the materials and plaster and casting wax loss process" Participant 1.

"I have a higher diploma in maxillofacial prosthetics from the University of Manchester. The only training I'm aware of currently is at King's College in London, where you can do an MSC in Maxillofacial prosthetics" Participant 1.

These interview quotes highlight challenges in obtaining maxillofacial prosthetics training in Ireland. While a dental technician course at the Dublin Dental Hospital offers a foundation, there seems to be no dedicated training program for maxillofacial prosthetics within the country.

"There is a dental technician course at the Dublin Dental Hospital, and the intake is six or seven students a year. Training in silicone prosthetics (soft tissue prosthetics) isn't available in Ireland," Participant 1.

Training on digital tools appears to be challenging, with no traditional CAD or digital sculpting tools in use. The manufacturing process is manual. One participant suggested that once the process is digitised, the department needs a trained expert. Additionally, these digital tools are not reconfigured as starting operating procedures.

"Once you digitise it (a prosthetic or patient impression), then you need to have proficiency in CAD and other digital tools" Participant 5.

This information suggests a gap in specialized maxillofacial prosthetics training within Ireland.

4.4 Objective 3

The interviews' findings highlighted one major theme to address: To examine whether a lack of knowledge and application use cases are associated barriers to entry with additive manufacturing adoption.

4.4.1 Theme Six: 3D Printed Surgical Aids

Additional maxillofacial tour findings uncovered 3D printed aids and tooling. 3D printable mandibles were on display. Participant 1 discussed how DICOM images could be used to print patient-specific mandibles for reconstructive and trauma surgical planning. Titanium plates are often shaped to fit a patient in the theatre. A 3D-printed surgical aid can allow titanium shaping off-site, meaning the shaped plate can be sterilised and delivered to the theatre, cutting down on operating times. This suggests that 3D printing has a place in a maxillofacial lab.

Similar surgical planning methods have been found in education, such as orthognathic surgery or corrective jaw surgery. Such procedures require additional years of training and may not be regularly performed by a maxillofacial surgeon. Participants 3 and 4 identified a use case for mandibles printed in bone-like material for surgical simulation. 3D printing and digital tools have been adopted into the simulation department. While 3D printing has played a significant role in tooling, jigs and fixtures, the participants have expressed interest in expanding the technology's use cases in surgical simulation. The participants have been exploring how 3D printing can help simulate robotic surgery, such as jigs, to allow students to solo practice robotic operation to anatomical correct models for hysterectomy simulation.

4.5 Review of Findings

The interviews with experts in the fields of medicine, education, innovation, and 3D printing delivered fascinating insights. The key findings have addressed the objectives, with further discussion on additive manufacturing integration into maxillofacial development to follow. The themes that emerged from the findings are:

- Theme 1: Patient Referral
- Theme 2: Current maxillofacial manufacturing process
- Theme 3: Retention methods
- Theme 4: Maintenance and aftercare
- Theme 5: Education
- Theme 6: 3D Printed Surgical Aids

5. Discussion

5.1 Introduction

The literature analysis revealed that 3D printing is an emerging area of interest in medicine, with rapid advancements in recent years. The trajectory of 3D printing technological advancements has been on a steep upward rise and is predicted to continue in years to come. The literature provided rich insights into the potential applications of 3D printing in medicine. However, direct-to-print 3D printable prosthetics still need research. Maxillofacial departments face the same challenges as Irish enterprises in adopting additive manufacturing technologies. The interviews provided a wealth of knowledge and highlighted an innovative mindset among practitioners who want to leverage the benefits 3D printing has to offer. The discussion chapter will highlight the findings, particularly the manufacturing theme; when broken down into its stages, areas of 3D printing benefits become apparent. Previous research will underpin the benefits and highlight the potential limitations of the technology. Criteria-based decision matrixes and failure mode analysis tools will compare the literature on 3D printed prosthetics against the currently established methods.

5.2 Objective 1

The first objective the interviews aimed to address was the current manufacturing methods. The literature review data provided an abstract view of how maxillofacial prosthetics are made. The rich interview data gave the researcher a low-level understanding of the processes. These methods will be discussed and mapped, and a proposed workflow for additive manufacturing integration will be explored. The proposed method takes learnings from the literature, the available manufacturing methodologies, and inspiration from the 3D printed prototypes developed for the interviews.

5.2.1 Theme 1: Manufacturing methods

The traditional process is artisanal and requires a skilled technician with years of training to imitate facial features. The training aspect already highlights a barrier to improving

manufacturing times, as a significant time investment is needed to qualify as a maxillofacial prosthetic technician. The interviewees categorised the manufacturing process into five appointments. Individual appointments focus on a stage of manufacturing, which can be simplified into the following stages: data collection, sculpting, negative mould, try-on, colour matching, casting, and postprocessing. Each completed stage brings the patient towards a finished prosthetic. The traditional workflow happens over several months due to scheduling constraints and time between exposing the implant.

A process map was drawn directly from the interview comments, and the interviewees described the process in great detail. When consulting the process map, it becomes clear that patient input is critical in manufacturing. After all, the patient will wear the prosthetic for life. The patient input has almost veto weight at specific appointments such as try-on, colouring, and fit appointments, with less weight on the impression appointment primarily focusing on accurate data capture, emphasising patient comfort. Should the patient be unhappy with the shape of the prosthetic, they will request changes, forcing the technician to rework the positive form or, worse, move back a couple of steps in the process map and try again. The try-on stage is when a patient can be most vocal,

“They often request lots of changes, too big, too small, it goes through a lot of tweaking”

The technician could use a combination of wax models or sample prosthetics for the try appointment. A sample prosthetic can not be changed in real time, but the wax model can. Shaping a wax model will take time, depending on the technician's skill level. 3D printing digital tools discussed in the proposed additive manufacturing workflow can speed up the patient input process by providing a virtual try-on via CAD, in which the patient can request changes to their prosthetic without attending a hospital appointment.

5.2.2 Improved Process Map with 3D Printing Integration

Few research papers have addressed the potential of 3D printing technology for creating maxillofacial prosthetics. Unkovskiy proposed a multi-material method for printing a silicone nose (2020). The limitations of the process were due to the nature of 3D printing itself. The

finished prints had surface artefacts that needed to be post-processed by hand to give a desired surface finish. It was a time-consuming process and required several passes of abrasive sanding and polishing. However, the research proved that CAD and digital design tools are suitable for the design process, which may save time in the manufacturing chain. The interviewees were shown a series of rapid prototypes to seek their opinions on how effective the methods by which they were designed.

5.2.3 Model to Print

A parametric model of a human head was used to develop the prosthetics. Previous research suggests mirroring the face's healthy side to repair the defect of a digitally scanned face (Unkovskiy et al., 2020)(Sherwood et al., 2020). The limitation with mirroring to cover a defect is that only orbital or aural prosthetics can be designed this way. This method is unsuitable for nasal prosthetics, which may require a scanned family member donor. Other researchers have suggested the idea of a digital repository of facial features for digital sculpting. This novel idea opens up areas of future research in creating and curating an open-source repository of constraint-based models, constraint-based models being parametric models that can limit the amount of modification. For example, using a slider, the user may adjust the nostril size or bridge width. A constraint-based system can be set up using popular CAD software such as Fusion360.

5.2.4 Meshmix and CAD

Starting with a human head model, it can be scaled to meet the dimensions of the patient. The following details a simple approach that can be used to remove a feature from the model for 3D printing a mould, try-on sample or potentially an interim prosthetic. A nose will be used as an example. The tools used in this process could be standardised, allowing technicians to learn the necessary CAD skills quickly. First, create a mirror line in the centre of the face. This will allow for an even selection. Using the selection tool, select the nasal region, including the boundary that interfaces with the orbital, infraorbital and frontal regions. The “expand or contract ring” modification tool can increase or decrease selection. Smoothing the ring when happy with the selection is advised using the “smooth boundary” tool. The selection can then be inverted using the “invert” tool. This will now select the remaining

model. The operator can delete the mesh to be left with a nose of zero thickness. A 3D mesh does not have an inherent thickness. It represents the surface geometry of an object, defined by vertices (points in space) and faces (connections between vertices). The offset tool can be used to add thickness. This creates a new surface by moving the existing mesh surface inwards at a specified distance.

By offsetting the mesh inwards, the user can create a watertight model for 3D printing by selecting “connected” and “preserve boundaries.” Now, an anatomical model of the nose is complete with relatively few steps.

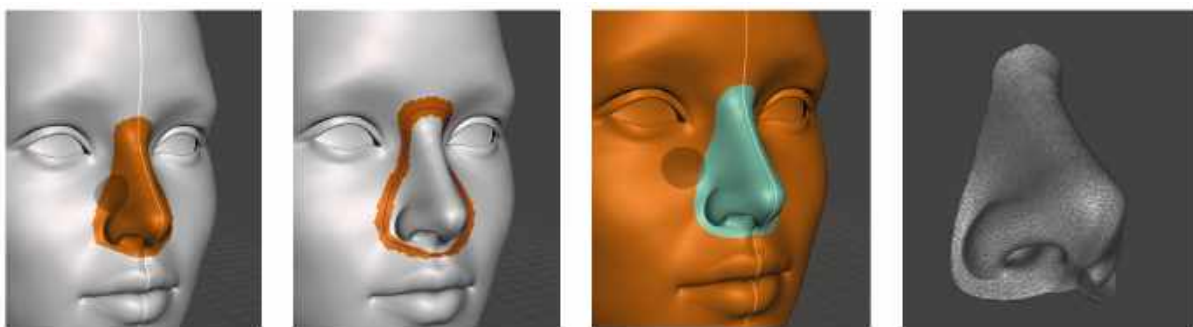


Figure 7. Removing anatomical features for printing.

5.2.5 Scanning

Alternatively, starting from a scan, should it be available, would be beneficial. Capturing facial scans with a handheld scanner requires practice, but several good cases have been put forward regarding its effectiveness. Ciocca (2023), Unkovskiy (2022) and Nuseir (2018) put forward best practices for scanning faces with different technologies. Hand-held laser light scanning proves to be an effective method for accuracy compared to photogrammetry methods. The proof of concepts and workflows put forward in research have varying degrees of complexity, some featuring expensive niche software, which is a barrier to entry. The best workflow incorporates various free and open-source software such as meshmixer. EinScan H, a hybrid scanner (LED light with invisible infrared light), was used to scan a patient and prove the effectiveness of handheld scanners in human body recreation. The scan accurately captured surface details around the orbital, intraorbital and frontal regions. However, the light was unsuitable for an in-depth scan of the defect or implant. Enough data is captured to use as

a manufacturing aid. However, the details would not suffice for surgical planning or record keeping due to the defect limitation. (photo of scan)

5.2.6 Slicing

This model could be used in the try-on appointment, or alternatively, the 3D render could show the patient their potential nose. The model could be overlaid on a potential scan of the patient. Sherwood (2020) suggests printing digital prototypes or models as manufacturing aids for use in traditional methods. It is important to stress the importance of proper print orientation. Sherwood and Unkovskiy printed their models in a suboptimal orientation, which is evident in the need for postprocessing. A model's orientation significantly impacts the visibility of Z layers, the horizontal lines created as the printer builds the object layer by layer. Printing a model with flat, angled surfaces facing upwards allows the filament to be deposited smoothly, minimising gaps between layers.

Conversely, printing a model with these surfaces facing the printer nozzle creates visible steps where new layers meet, making the Z layering more prominent. By strategically orienting the model to minimise large, flat areas facing upwards, it achieves a smoother final print with less Z-layer visibility and, thus, less processing. It is important to note that printing this nose upright in its natural position takes longer and may require more support material. The results and aesthetics are better, and the time needed for postprocessing is reduced. Ultimaker Cura 5.6.0 was used to slice the models for 3D printing.

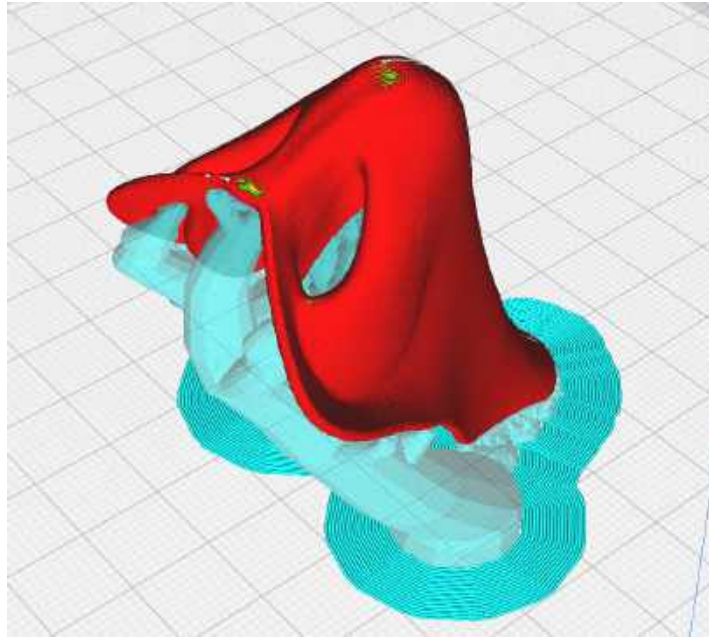


Figure 6. Model slicing for optimal Z layers.

Unfortunately, traditional FDM printing is mono-colour, and the flocking effect described by the participants can not be replicated.

"Through that effect (red flocking), the prosthetics achieve versatility across ranges of skin types"

The flesh-coloured prototype was introduced to surface noise during the modelling stage using Formlabs Texture Engine. The texture engine applied a displacement map to the surface of a model (Formlabs, 2024). The map can be modified to mimic the texture of the human skin (Tymms et al., 2018). Adding this texture and noise to the model helps to disguise the Z-layer lines, giving the effect of traditional silicone prosthetics. More research in displacement maps is needed to prove the effectiveness of 3D printable textures, but this example proved promising.

5.2.7 Printing

As mentioned, orientation plays a crucial part in preparing the model for printing, and previous case studies and literature often fail to identify best practices for printing. This could be due to multidisciplinary research teams, who may not consult external additive

manufacturing experts for advice. Printing can be subjective and highly dependent on desired outcomes. An Ultimaker S3 was used to print the models. This machine is an enterprise machine designed for repeatable results. The table below details the operating conditions for the prototypes and why.

Model: Prosthetic noses, both white and flesh.

Variable:	Setting:	Why:
Material	TPU	Flexible, Shore D hardness of 90. It resembles a very rigid silicone but is widely available.
Nozzle size	0.4mm	Suitable for 100-micron layer height models with thin walls.
Infil	N/A	The model's thickness was 1mm, meaning infill is unnecessary due to wall count.
Layer height	0.1mm	Lowest reliable layer height achievable with TPU.
Adhesion	Yes, brim only, no adhesive	The adhesive was unnecessary due to the glass build plate and brim use.
Support	Yes, tree supports	The model was printed 180 degrees from the natural position to reduce artefacts from layer lines and interface artefacts from support structures.
Wall count	2	Max number of walls possible.
Print time	59mins	Cura 5.6.0 has optimised profiles for TPU printing. With some speed adjustments, the time could be reduced.
Cost	8grams/ €0.47	The price of material fluctuates but is inexpensive per kilogram.



Figure 7. TPU Printed prosthetic noses.

Model: 3D scan manufacturing aid, Grey.

Variable	Setting	Why
Material	PLA	Rigid plastic, low melting point and easy to use. High printing accuracy.
Nozzle size	0.4mm	Suitable for 100-micron layer height models with thin walls.
Infil	15%	This allows for faster print times, and the top surface layers do not require additional support.
Layer height	0.1mm	A blend of model detail and print time. PLA can reliability go down to 0.06mm, but time increases (roughly 1.67 times slower)
Adhesion	No	The model has a large surface area in contact with the build plate.
Support	No	The model does not have overhangs greater than 45 degrees.

Wall count	3	Improve object stiffness without drastically increasing material usage or print time.
Print time	8 hours 25 minutes	Cura 5.6.0 has optimised profiles for PLA printing. With some speed adjustments, the time could be reduced.
Cost	93grams/ €4.96	The price of material fluctuates but is inexpensive per kilogram.

CAD and 3D printing can improve the speed of maxillofacial prosthetics and rehabilitation by facilitating several steps: the impression, the design of complex anatomical models, the try-on, and the creation of a mould. Comments from the interviewees suggest that 3D printing has a place within the maxillofacial department, not only in the manufacturing process but as an interim solution to improve patient mental health and recovery outcomes.

5.2.8 Pugh Analysis

A Pugh analysis, also known as the Pugh Matrix or Pugh concept selection process, compares and evaluates different options for a design, product, or process. It helps to systematically identify the best option based on a set of criteria and select the optimal concept from a list of alternatives by systematically comparing them against each other. This Pugh matrix will be compared against our baseline. The baseline consists of the currently established manufacturing methods, and the concepts will consist of the research samples printed as part of the interviews and previous research.

	Importance Rating	Current prosthetic method	Research Samples	Sherwood et al., 2020	Cicco et al., 2023	Nuseir et al., 2019
Time	10	Baseline	+	+	\$	-
Cost	5	Baseline	+	+	-	-
Material Selection	7	Baseline	-	-	+	\$
Feel	8	Baseline	-	-	+	+
Tooling	4	Baseline	\$	\$	\$	\$
Aesthetics	7	Baseline	\$	-	\$	\$
Production Rate	5	Baseline	+	+	+	-
Comfort	10	Baseline	-	-	-	\$
Safety	10	Baseline	-	-	\$	\$
Retention	10	Baseline	\$	\$	-	\$
Function	9	Baseline	\$	\$	\$	\$
Sum of Positives			3	3	3	3
Sum of Negatives			4	5	3	4
Sum of Sames			3	3	5	4
Weighted Sum of Positives			20	20	20	8
Weighted Sum of Negatives			25	42	25	20
TOTALS			-5	-22	-5	-12

Figure 8. PUGH Analysis

Five concepts were compared to the current manufacturing method, representing the baseline. One of the concepts is the rapid prototype samples produced for the interview. The other four concepts are based on previous research. The papers were chosen as the aims aligned research, and the papers produced working prototypes. This allows for a cross-evaluation of different maxillofacial prosthetics made with 3D printing. The design criteria address the following needs:

Time Benefit	Does the concept take less time to manufacture compared to the baseline
Cost	Does the concept cost more to manufacture
Material Selection	Does the concept meet the material requirement set out by the baseline
Feel	Does the concept mimic the feel of the missing feature
Tooling	Does the concept meet tooling requirements
Aesthetics	Does the concept match aesthetic standards set out by the baseline
Production Rate	Does the concept have an improved production rate against the baseline

Comfort	Does the concept have the same comfort level as the baseline
Safety	Does the concept use safe materials
Retention	Does the concept use the same retention methods as the baseline
Function	Does the concept improve or repair the lost bodily function

The PUGH matrix shows that additive manufacturing technologies are advancing to replicate the results of the current methods. Low-cost FDM printers were used in this paper and by Sherwood (2020), which demonstrated the positive time benefits of FDM printing. However, the results show that the materials used in FDM printing differ from traditional silicone's softness and intrinsic colouring ability. Still, they show promising results in aiding manufacturing and patient outcomes. Cicco (2023) and the team had exciting results due to their multi-material method. The team printed the prosthetic and relined it with PDMS silicone. It meets the needs. However, the retention methods relied on a titanium-printed bracket attached to eyewear. This is expensive and suboptimal for retention, as the eyewear is liable to move. This relining method highlights a future area of study, with retention being a key focus for this method. Lastly, Nuseir's (2019) results proved to be a close match for the traditional methods. They could print directly in silicone using an experimental technique of Drop-on-Demand printing by WACKER. This method's limitation is the print's roughness, which needs to be further relined and coloured, adding time to production. Furthermore the printer is expensive and had to be outsourced. Overall, each method has a lot to offer future research.

5.2.8 Process map

The interviews have highlighted areas where 3D printing and its associated technologies could be integrated. With the current state established, following the HSE process mapping guidelines and quality improvement toolkit. The HSE toolkit promotes a three-block improvement process. Block one establishes the “current state” map of the process identified. Block two establishes a “future state” map of the process, enabling the changes required to improve the process. Block three develop a gap analysis that will identify the actions required to get from the “as is” current state to the “ideal” future state (HSE, 2019). A new future state

process map can be drawn. The process map below incorporates the interview findings, research, and comments on the effectiveness of the interview samples.

The new process map aims to remove the need for one of the five appointments. The process suggests incorporating 3D scanning into the first appointment, the “expose implant” appointment. This will give the technician a head start on digital sculpting before the next appointment. The two-week healing abutment phase is still required. For the second appointment, a secondary scan can be taken for record keeping. The patient will be shown examples of their prosthetic on a laptop, designed over the two-week healing phase. The patient can consult on the appearance of the prosthetic. Ideally, any adjustments would be made digitally. Once happy, a sample can be printed, referencing the TPU sample above. A total print time of 1 hour is needed. The patient can stay in the hospital while the print is finished. Participant 1 stated that printing would be desirable for the try-on phase:

"The next appointment would be to try on a nose, something somebody might have printed for me. See, did the patient like it?"

The patient can then try on their TPU printed sample, which will accurately represent the final silicone prosthetic shape. Should the try-on be a success, the patient is free to leave with the sample that can be retained on the face via an elastic. Participant 1 stated that the TPU sample could easily incorporate an elastic retention method for short-term wear. The ideal process involves two appointments to prototype, design and receive patient feedback. Using the data capture and the files prepared for the try-on, the technician can begin manufacturing a suitable long-term silicone prosthetic. A 3D printable mould can be printed to cast the silicone, which can be efficiently designed by performing a boolean subtraction between the prosthetic and mould block in Meshmixer. SLA may be a viable option for mould making, with its ability to print lower resolutions, and its integration into surgical planning has proven its application (Eshkalak et al., 2020)(Mallon et al., 2023). The technician can continue with their traditional manufacturing methods. In practice, a second appointment may be removed from the process. The curing times for the silicone vary depending on the methods used and can be as short as 2 hours if a high-temperature vulcanisation method is used. This means a patient could wait in the hospital and remove the need to return for another appointment. A new process map can be seen in Figure 9.

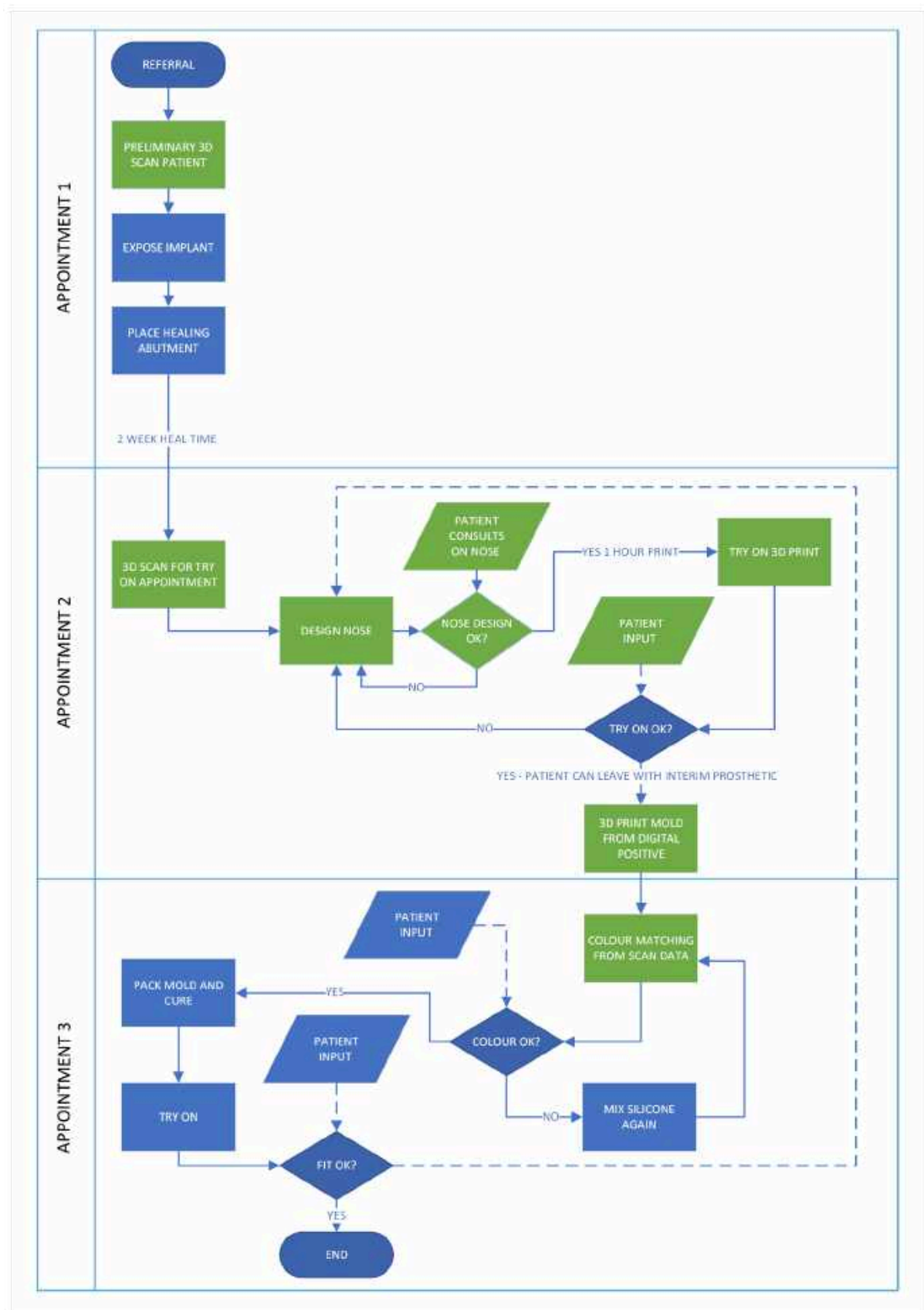


Figure 9. New proposed process map with 3D printing integration.

5.3 Objective 2

The second objective aimed to address the resources needed to improve the integration of additive manufacturing technologies. The literature argues that 3D printing technology is more than capable. However, the technology on the market has proven to be diverse. The interviews discovered that maintenance and education are key issues. If resources were devoted to addressing these concerns, adoption rates of 3D printing could improve.

5.3.1 Theme Four: Maintenance and Aftercare

The interview participants echoed a vital point: “Patients who need a prosthetic become patients for life.” The participants are unsure of the exact number of new admittances to the department as it varies yearly. The literature states that the need for maxillofacial prosthetics is rising, highlighting a potential strain on the system in years to come (Li et al., 2023). A prosthetic needs maintenance or recasting every two years due to UV light exposure or edge strength failure, a common cause across all prosthetics (Li et al., 2023)(Powell et al., 2020).

“The discolouration varies depending on the person, but typically 2 to 3 years before a replacement is needed.”

The participants stated that a recast is a simple process should the patient's face remain unchanged.

“It would be difficult to bond something onto the silicone, and there is not much material anyway, so it is just easier to make a new one.”

Having a digital historical scan and prosthetic on file makes adjustments easy. The agreed-upon prosthetic the patient previously consulted on could be reworked to fit a new 3D scan should the patient's face change drastically. Then, the process can be repeated, taking this digital prosthetic and bringing it to life via the established methods. A consultant surgeon carries out maintenance around the skin and implants and is outside this project's scope. It is important to note as it highlights the recurring nature of treating patients with maxillofacial defects.

5.3.2 Theme Five: Education

Once part of the process becomes digital, the team responsible for manufacturing prosthetics must upskill or outsource. The digital element of the proposed workflow could be handled by another department or function within the hospital. Participant 5 suggested that the digital process could “be supported via a design unit already in place in a hospital.” Multi-disciplinary teams are responsible for delivering patient care, and the future of maxillofacial prosthetics will incorporate digital tools (Nyberg et al., 2016). Educational resources for CAD and 3D printing in a maxillofacial discipline are not currently available in Ireland. Participants 3 and 4 expressed the desire to integrate CAD and 3D printing into their universities' programs and simulation classes. The lack of training within Ireland could have a future impact on maxillofacial prosthetics in Ireland. The interviews and tour of a maxillofacial department emphasised the learnings from the literature review. Maxillofacial prosthetics are artistic representations of human anatomy (Miechowicz et al., 2020). The artistic nuances may be challenging to transfer as a practitioner develops these skills over years of practice.

5.3.3 Resources - Failure Mode and Effects Analysis

FMEA stands for Failure Mode and Effects Analysis. It is a systematic approach to identifying potential weaknesses or failures in a system, process, or product. It is a good tool for aiding additive manufacturing integration into a maxillofacial department. FMEA helps identify potential problems before they occur during the implementation process. This allows resource planning to mitigate those risks and ensure a smoother transition. When implementing a new technology, resource needs can be multifaceted. An FMEA in this context helps to identify the specific resources required to address potential failure modes. The FMEA assigns a Risk Priority Number (RPN) to each failure mode. This number considers the severity, occurrence, and detectability of the issue. This helps prioritise which potential problems require the most attention when allocating resources. The FMEA framework typically involves different departments working together to identify and address potential failures, fostering better communication and collaboration during the implementation phase. A limitation of the FMEA framework is cross-department collaboration, and certain assumptions must be made. A potential area of future research

would be a multi-department FMEA analysis for additive manufacturing integration in a hospital setting. Figure 10 details the FMEA results.

Item Name: Maxillofacial - Additive Manufacturing Integration		FMEA Team: Maxillofacial Department / HSE				Prepared by: N/A								
						FMEA Date (Orig): 01.04.2024						Revision #: 1		
Process Step or Variable or Key Input	Potential Failure Mode	Potential Effect on Customer Because of Defect	S E V	Potential Causes	O C C	Current Process Controls	D E T	R P N	Actions Recommended	Resp.& Target Date	S E V	O C C	D E T	Future RPN
What is the process step?	In what ways can the Process Step, Variable, or Key Input go wrong? (chance of not meeting requirements)	What is the impact on the Key Output Variables (customer requirements) or internal requirements?	How Severe is effect to the customer?	What causes the Key Input to go wrong? (How could the failure mode occur?)	How frequent is cause likely to Occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is Detection of cause?	Risk Priority # to rank order concerns	What are the actions for reducing the Occurrence of the cause, or improving Detection?	Who's Responsible for the recommended action? What date?	Future Severity	Future Occurance	Future Detection	
3D Scanning and image capture	1. Poor lighting of the patient. 2. Sudden movement of the patient. 3. Scanner to PC connection loss. 4. Glossary surfaces. 5. Poor image capturing.	Process Robusness and repeatability, Process Efficiency	10	Human error. Process variability. Faulty component.	8	Training on new type of equipment / enviromental setup.	6	480	1. Procedures to ensure accurate image capture per ISO 20685-1. 2. Dental chair with restraints to prevent movement. 3. Equipment calibration to remove the risk technical faults. 4. Training procedures in place for staff. 5. Training procedures in place for staff.	Maxillofacial Department / HSE	10	2	4	80
FDM 3D Printing	1. Incorrect material fed into the printer. 2. Yield loss. 3. Poor print strength. 4. Material blockages. 5. Unsuccessful prints. 6. Poor bed adhesion. 7. Appearance	Process variability	10	Human error. Machine error. Poor maintance of printer. Environmental factors. Calibration incomplete.	6	Training on new type of equipment / enviromental setup.	3	180	Detailed SOPs to guide users through the printing process. A maintenance schedule will ensure proper maintenance and calibration of the printer. Materials will be stored properly and labelled.	Maxillofacial Department / HSE	5	2	1	10
3D Mesh processing	1. Lost files. 2. Poor processing techniques. 3. Corrupt files.	Process Robusness and repeatability, Process Efficiency	8	Human error. Process variability.	7	Training on new type of equipment / enviromental setup.	2	112	1. Data will be backed up to 2 separate locations. 2. Training provided on how to use the software, and SOPs are written for reference. 3. Files will have duplicate backups, and equipment will be maintained.	Maxillofacial Department / HSE	8	2	1	16
Slicing	1. Poor technique. 2. Incorrecr settings. 3. Underwater tight mesh. 4. Long lead times.	Process Robusness and repeatability, Process Efficiency	7	Human error.	4	Training on new type of software.	2	84	Detailed SOPs to guide users through the slicing process and file preparation process.	Maxillofacial Department / HSE	5	2	1	10
Design Limitations	3D printed models incompatible with software or exhibit unexpected design flaws.	Process variability, Process Robusness and repeatability, Process Efficiency	8	Human error.	5	Training on new type of equipment / enviromental setup.	1	40	Invest in design software compatible with 3D printers. Involve technicians in the design process to identify potential limitations early on. Pilot testing of 3D printed models before wider adoption.	Maxillofacial Department / HSE	4	2	1	8
Material compatibility issues	Resins or filaments used in 3D printing cause allergic reactions in patients or prove unsuitable for tooling applications.	Process Robusness and repeatability, Process Efficiency	10	Human error. Process variability. Faulty component.	10	Training on new type of equipment / enviromental setup.	1	100	Thorough research on biocompatible and dentally-approved materials. Sample testing of materials before using them with patients.	Maxillofacial Department / HSE	4	1	1	4

From the FMEA, it is clear that training will be the most significant resource required. Adding various technologies, such as CAD software, design software, slicing software, 3D scanning, FDM or SLA printing, requires niche knowledge. A training partner or institution is required to upskill staff on the technology. Aside from the training required, decisions will need to be made on the technological requirements to meet the needs of the maxillofacial department. This research has answered how additive manufacturing can advance maxillofacial prosthetics in Ireland, going as far as prototype proof of concepts. Additional research is needed into the needs of the technology.

5.4 Objective Three:

The final objective examines whether a lack of knowledge and application use cases are associated barriers to entry with additive manufacturing adoption. The literature proved that this is not the case. Several journals and medical research centres worldwide are actively researching additive manufacturing technologies. The literature highlighted a need for maxillofacial and additive manufacturing research, but the technology is heavily studied in other medical fields. The interviews proved that additive manufacturing is on the minds of education practitioners and medical professionals.

5.4.1 Theme Six: 3D Printed Surgical Aids

The literature showed several examples of 3D-printed surgical aids in use worldwide and in Ireland. One study by a business based in Northern Ireland printed a nasal polyp and frontal region of the skull, improving the patient's surgical outcome (Mallon et al., 2023). The interviews detailed a requirement for this service in the future, with education taking an early adoption of printing for surgical planning and simulation. It is important to note that external companies primarily offer surgical planning aids as a service. The limitation is the turnaround time for preoperative planning. Such services could be easily integrated into a hospital environment, bringing in-house service. This is outside the scope of the research, but it emphasises the additional use cases of additive manufacturing. With several medical applications already becoming established in other countries, this builds a significant business case for the HSE. An additive manufacturing setup for a maxillofacial department could be

used for preoperative planning when not in use. Additionally, the skills are transferable across departments.

The FMEA discovered the educational need to implement additive manufacturing integration. Education would help bridge the gap in identifying applications. Suppliers of 3D printing equipment need to help users identify their applications.

5.5 Discussion Summary

Traditionally, creating maxillofacial prosthetics is a highly skilled and time-consuming process. Patients undergo multiple appointments with a technician who meticulously collects data, sculpts the prosthetic, creates a negative mould, conducts try-on sessions for adjustments, matches skin colour, casts the final product, and performs post-processing. Patient input is crucial throughout this process, often leading to revisions to ensure a perfect fit and natural appearance. 3D printing offers a glimpse into a future where this process can significantly improve. Research suggests that 3D printing can accelerate the workflow, allowing for more intricate designs and a more patient-centred experience. Studies exploring multi-material printing and advanced digital design tools promise even greater advancements. 3D scanning technology can capture highly detailed facial data for superior prosthetic accuracy, while printing techniques like FDM and SLA can be used to create prototypes and even manufacturing aids. The proposed workflow using 3D printing envisions integrating 3D scanning into the initial appointment to kickstart the digital sculpting process. Patient consultations would then refine the digital model, creating a 3D printed try-on sample for fine-tuning. Finally, a 3D-printed mold would be used to cast the final silicone prosthetic. This streamlined workflow has the potential to significantly reduce the number of appointments patients need to undergo while also improving the overall outcome and patient satisfaction.

5.6 Review of discussion:

The discussion of the findings chapter evaluates the data, insights, and expertise of the participants. Combined with what was learned from the literature review, the author has been awarded a low-level understanding of the challenges in integrating additive manufacturing in Ireland's maxillofacial departments. The discussion put forward a process for integrating additive manufacturing into the current state and, from this, will draw conclusions and recommendations to accomplish the challenge of advancing Ireland's maxillofacial prosthetics with additive manufacturing.

6. Conclusion

This chapter presents a comprehensive overview of the key points covered in the study on maxillofacial prosthetics. The study aimed to identify the existing value chain of maxillofacial manufacturing in Ireland and recommend methods for improving the process through additive manufacturing, an innovative field with the potential to enhance medical procedures. The study employed a qualitative approach, utilising expert interviews from the industry and prototypes based on the literature review findings. The analysis identified gaps in the current state that could be addressed through additive manufacturing, and the interviews highlighted themes that addressed the study's three objectives.

The interview thematic analysis reveals valuable insights into current practices of maxillofacial prosthetics in Ireland and potential areas for improvement using additive manufacturing. The Irish healthcare system needs to clarify referral pathways for maxillofacial prosthetics. Some patients must be aware of available services and may require self-advocacy or travel to the UK. The traditional process is manual, time-consuming (4-6 months), and involves multiple patient appointments for impression-taking try-on sessions and colour matching. Prosthetics require regular replacements (every 2-3 years) due to discolouration and require ongoing skin maintenance around implants. Training opportunities in maxillofacial prosthetics are limited in Ireland, with no dedicated programs and challenges in digital tool training. 3D printing is already used for surgical planning tools (e.g., mandibles) but not for prosthetics themselves. Participants expressed interest in exploring its potential in surgical simulation. The findings suggest that 3D printing can improve efficiency, personalisation, and potentially even patient outcomes in maxillofacial prosthetics. However, challenges exist regarding education, traditional workflows, and a lack of awareness of 3D printing's capabilities within the healthcare system.

The study on maxillofacial prosthetics faced limitations, including a small sample size that only included prosthodontics, prosthetic technicians, and maxillofacial consultants in Ireland. As a result, the findings may have limited scope and may not apply to other prosthetic scenarios. The research should have also discussed the cost implications of the technology, considering the various options available in the market. While 3D printing may save time, the initial investment in equipment may be significant. The research has suggested low-cost FDM printing as an alternative. Another critical area for consideration is the long-term

durability of TPU-printed prosthetics compared to traditional methods. While TPU may be suitable for interim prosthetics, further research is necessary to determine its durability as a prosthetic or its safety for prolonged body contact. Unfortunately, the study did not include patient input and satisfaction due to ethical considerations, and the discussion did not explore patient satisfaction with 3D-printed prosthetics.

This research makes several recommendations. One is to develop training programs to equip maxillofacial professionals with the skills and knowledge to leverage additive manufacturing technologies effectively. Dedicated educational resources must promote knowledge sharing via industry clusters to support this training program and establish best practices for additive manufacturing in maxillofacial applications. Industry can play a pivotal role in helping medical professionals leverage the technology. Before investing, a cost-benefit analysis should assess the long-term economic impact of implementing additive manufacturing in maxillofacial prosthetics in Ireland.

This research is essential to justify research infrastructure, which should be established to support the exploration and development of additive manufacturing technologies. In Ireland, several research centres are focused on additive manufacturing for the industry. Investing in pilot programmes with research centres will help additive manufacturing integrate into maxillofacial prosthetics. Lastly, collaboration between stakeholders, healthcare professionals, engineers, and policymakers is needed to create a supportive ecosystem for integrating additive manufacturing printing into maxillofacial care.

This research set out to establish the current methods and how they can be improved with additive manufacturing. Future research areas are needed in the field, and the author makes the following predictions for future study.

1. Material Science and Biocompatibility:

The development of new 3D printing materials that mimic the natural properties of skin and tissues is underway. This will improve the aesthetics, comfort, and durability of prosthetics.

2. Advanced Printing Techniques:

Research should explore multi-material printing to create prosthetics with different textures and functionalities within a single structure. This will help replicate natural facial features more closely.

3. Integration with Artificial Intelligence (AI):

AI could personalise and optimise prosthetic designs based on patient data and facial scans, resulting in a perfect fit and natural appearance. Additionally, AI-powered tools are being developed to automate aspects of the 3D printing workflow, such as design optimisation and post-processing, for increased efficiency.

4. Clinical Trials and Patient Outcomes:

Large-scale clinical trials need to be conducted to evaluate the long-term effectiveness and durability of 3D-printed prosthetics compared to traditional methods. Researchers are also studying the psychological impact of 3D-printed prosthetics on patients' self-esteem, social interaction, and overall quality of life.

5. Cost-Effectiveness Analysis:

Compared to traditional methods, an in-depth cost-effectiveness analysis is needed to assess the long-term economic impact of 3D printing in maxillofacial prosthetics. This includes analysing initial investment costs and potential savings in appointment times, materials, and patient care needs.

6. Workflow Optimisation and Standardisation:

Best practices must be researched, and standardised workflows are being developed to integrate 3D printing into maxillofacial treatment procedures. This will result in efficient and consistent clinical outcomes and will involve optimising communication and collaboration between healthcare professionals involved in the process.

7. References:

- Al-Dharrab, A.A., Tayel, S.B. and Abodaya, M.H. (2013). The Effect of Different Storage Conditions on the Physical Properties of Pigmented Medical Grade I Silicone Maxillofacial Material. *ISRN Dentistry*, 2013, pp.1–9.
doi:<https://doi.org/10.1155/2013/582051>.
- Arrieta, M.P. (2021). Influence of Plasticizers on the Compostability of Polylactic Acid. *Journal of Applied Research in Technology & Engineering*, 2(1), p.1.
doi:<https://doi.org/10.4995/jarte.2021.14772>.
- Braun, V. and Clarke, V. (2006). Using Thematic Analysis in Psychology. *Qualitative Research in Psychology*, [online] 3(2), pp.77–101.
doi:<https://doi.org/10.1191/1478088706qp063oa>.
- Chinta, A., MC, S.S., Rao D, B., Raju Mantena, S., Kumar PV, R. and Kondaveeti, B. (2022). Prosthodontic rehabilitation of a mucormycosis patient: a case report. *International Journal of Dental Materials*, 04(04), pp.98–101.
doi:<https://doi.org/10.37983/ijdm.2022.4405>.
- Ciocca, L., Emiliani, N., Artuso, G., Breschi, L., Marcelli, E. and Cercenelli, L. (2023). An Update of Eyeglasses-Supported Nasal–Facial Prosthetic Rehabilitation of Cancer Patients with Post-Surgical Complications: a Case Report. *Applied sciences*, 13(8), pp.4944–4944. doi:<https://doi.org/10.3390/app13084944>.
- Crafts, T.D., Ellsperman, S.E., Wannemuehler, T.J., Bellicchi, T.D., Shipchandler, T.Z. and Mantravadi, A.V. (2016). Three-Dimensional Printing and Its Applications in Otorhinolaryngology–Head and Neck Surgery. *Otolaryngology–Head and Neck Surgery*, 156(6), pp.999–1010. doi:<https://doi.org/10.1177/0194599816678372>.
- Cruz, R.L.J., Ross, M.T., Powell, S.K. and Woodruff, M.A. (2020). Advancements in Soft-Tissue Prosthetics Part B: the Chemistry of Imitating Life. *Frontiers in Bioengineering and Biotechnology*, [online] 8, p.147.
doi:<https://doi.org/10.3389/fbioe.2020.00147>.
- Destruhaut, F., Caire, J.-M., Dubuc, A., Pomar, P., Rignon-Bret, C. and Naveau, A. (2021). Evolution of Facial prosthetics: Conceptual History and Biotechnological

Perspectives. *International Journal of Maxillofacial Prosthetics*, [online] 4, pp.2–8.
doi:<https://doi.org/10.26629/ijmp.2021.02>.

European Patent Office (2023). Patent Filings in 3D Printing Grew Eight Times Faster than Average of All Technologies in Last Decade | Epo.org. [online] www.epo.org. Available at:
<https://www.epo.org/en/news-events/news/patent-filings-3d-printing-grew-eight-times-faster-average-all-technologies-last#:~:text=in%20last%20decade-> [Accessed 21 Apr. 2024].

Engin Sakarya, Kar, M. and Sameer Ali Bafaqeeh (2020). Surgical Anatomy of the External and Internal Nose. *All around the Nose*, pp.39–47.
doi:https://doi.org/10.1007/978-3-030-21217-9_4.

Eshkalak, S.K., Ghomi, E.R., Dai, Y., Choudhury, D. and Ramakrishna, S. (2020). The Role of three-dimensional Printing in Healthcare and Medicine. *Materials & Design*, [online] 194, p.108940. doi:<https://doi.org/10.1016/j.matdes.2020.108940>.

Ferneini, E.M., Hapelas, S., Watras, J., Ferneini, A.M., Weyman, D. and Fewins, J. (2017). Surgeon's Guide to Facial Soft Tissue Filler Injections: Relevant Anatomy and Safety Considerations. *Journal of Oral and Maxillofacial Surgery*, 75(12), pp.2667.e1–2667.e5. doi:<https://doi.org/10.1016/j.joms.2017.08.026>.

Flick, U. (2015). Qualitative Inquiry—2.0 at 20? Developments, Trends, and Challenges for the Politics of Research. *Qualitative Inquiry*, 21(7), pp.599–608.
doi:<https://doi.org/10.1177/1077800415583296>.

Formlabs (2023). *100% Silicone 3D Printing Made Accessible: Introducing Silicone 40A Resin*. [online] Formlabs. Available at:
<https://formlabs.com/eu/blog/silicone-3d-printing-material-silicone-40a-resin/> [Accessed 5 Dec. 2023].

Ghadimi, P., Donnelly, O., Sar, K., Wang, C. and Azadnia, A.H. (2022). The Successful Implementation of Industry 4.0 in manufacturing: an Analysis and Prioritization of Risks in Irish Industry. *Technological Forecasting and Social Change*, 175, p.121394.
doi:<https://doi.org/10.1016/j.techfore.2021.121394>.

- Hashiguchi, S., Hayakawa, K., Inoue, E., Han, A., Iwanaga, J., Tabira, Y., Yamashita, A., Hideaki Rikimaru, Kensuke Kiyokawa and Watanabe, K. (2022). An Anatomical Dissection Method for Observation of Fibrous Facial Structures. *Plastic and Reconstructive Surgery*, 151(3), pp.569–579.
doi:<https://doi.org/10.1097/prs.00000000000009975>.
- Hong, C.H., Kim, S.H., Seo, J.-Y. and Han, D.S. (2012). Development of Four Unit Processes for Biobased PLA Manufacturing. *ISRN Polymer Science*, 2012, pp.1–6.
doi:<https://doi.org/10.5402/2012/938261>.
- Ioannidis, J.P.A. (2005). Why Most Published Research Findings Are False. *PLoS Medicine*, 2(8).
- Kantaros, A., Ganetsos, T. and Piromalis, D. (2023). 3D and 4D Printing as Integrated Manufacturing Methods of Industry 4.0. *American Journal of Engineering and Applied Sciences*, 16(1), pp.12–22. doi:<https://doi.org/10.3844/ajeassp.2023.12.22>.
- Karasik, E., Fattal, R. and Werman, M. (2019). Object Partitioning for Support-Free 3D-Printing. *Computer Graphics Forum*, 38(2), pp.305–316.
doi:<https://doi.org/10.1111/cgf.13639>.
- Kaushik, V. and Walsh, C.A. (2019). Pragmatism as a Research Paradigm and Its Implications for Social Work Research. *Social Sciences*, 8(9).
- Kiat-amnuay, S., Jacob, R.F., Chambers, M.S., Anderson, J.D., Sheppard, R.A., Johnston, D.A., Haugh, G.S. and Gettleman, L. (2010). Clinical Trial of Chlorinated Polyethylene for Facial Prosthetics. *The International Journal of Prosthodontics*, [online] 23(3), pp.263–270. Available at: <https://pubmed.ncbi.nlm.nih.gov/20552094/> [Accessed 5 Dec. 2023].
- Lanzara, Dr.R., Viswambaran, Dr.M. and Kumar, Dr.D. (2021). Maxillofacial Prosthetic materials: Current Status and Recent advances: a Comprehensive Review. *International Journal of Applied Dental Sciences*, 7(2), pp.255–259.
doi:<https://doi.org/10.22271/oral.2021.v7.i2d.1219>.
- Lanzara, R., M Viswambaran and Kumar, D. (2022). Effect of Disinfection on the Physical Properties of Maxillofacial Silicone Material : a Systematic Review. *PARIPEX*

INDIAN JOURNAL OF RESEARCH, 11(11), pp.64–69.

doi:<https://doi.org/10.36106/paripex/1905905>.

Li, X., Xu, J., Fan, J., Xue, Y., Gu, X., Zhou, H. and Han, D. (2023). Current Situation and Development of Facial Prosthesis. *Chinese Journal of Plastic and Reconstructive Surgery*, 5(1), pp.39–42. doi:<https://doi.org/10.1016/j.cjprs.2023.03.005>.

Mallon, A. and Farnan, T. (2021). A Case Report Detailing the Use of 3D Printing Technology in Surgical Planning and Decision Making in ENT surgery-an Axial 3D First in Northern Ireland. *International Journal of Surgery Case Reports*, 87, p.106407. doi:<https://doi.org/10.1016/j.ijscr.2021.106407>.

Mao, K., Meng, Z.-Q. and Zhang, Y.-B. (2022). Progress on the regulation of neural crest and the genetics in craniofacial development. *PubMed*, 44(12), pp.1089–1102. doi:<https://doi.org/10.16288/j.ycz.22-221>.

Miechowicz, S., Wojnarowska, W., Majkut, S., Trybulec, J., Pijanka, D., Piecuch, T., Sochacki, M. and Kudasik, T. (2021). Method of Designing and Manufacturing Craniofacial Soft Tissue Prostheses Using Additive Manufacturing: a Case Study. *Biocybernetics and Biomedical Engineering*, [online] 41(2), pp.854–865. doi:<https://doi.org/10.1016/j.bbe.2021.05.008>.

Mitra, A. (2014). Maxillofacial Prosthetic Materials- an Inclination Towards Silicones. *Journal of Clinical and Diagnostic Research*, 8(12). doi:<https://doi.org/10.7860/jcdr/2014/9229.5244>.

Naftali, S., Rosenfeld, M., Wolf, M. and Elad, D. (2005). The Air-Conditioning Capacity of the Human Nose. *Annals of Biomedical Engineering*, [online] 33(4), pp.545–553. doi:<https://doi.org/10.1007/s10439-005-2513-4>.

Ngo, T.D., Kashani, A., Imbalzano, G., Nguyen, K.T.Q. and Hui, D. (2018). Additive manufacturing (3D printing): A review of materials, methods, applications and challenges. *Composites Part B: Engineering*, [online] 143, pp.172–196. doi:<https://doi.org/10.1016/j.compositesb.2018.02.012>.

Nuseir, A., Hatamleh, M.M., Alnazzawi, A., Al-Rabab'ah, M., Kamel, B. and Jaradat, E. (2018). Direct 3D Printing of Flexible Nasal Prosthesis: Optimized Digital Workflow

- from Scan to Fit. *Journal of Prosthodontics*, 28(1), pp.10–14.
doi:<https://doi.org/10.1111/jopr.13001>.
- Nyberg, E.L., Farris, A.L., Hung, B.P., Dias, M., Garcia, J.R., Dorafshar, A.H. and Grayson, W.L. (2016). 3D-Printing Technologies for Craniofacial Rehabilitation, Reconstruction, and Regeneration. *Annals of Biomedical Engineering*, 45(1), pp.45–57. doi:<https://doi.org/10.1007/s10439-016-1668-5>.
- OECD (2023). *Health at a Glance 2023. Health at a glance*.
doi:<https://doi.org/10.1787/7a7afb35-en>.
- Powell, S.K., Cruz, R.L.J., Ross, M.T. and Woodruff, M.A. (2020). Past, Present, and Future of Soft-Tissue Prosthetics: Advanced Polymers and Advanced Manufacturing. *Advanced Materials*, 32(42), p.2001122. doi:<https://doi.org/10.1002/adma.202001122>.
- Proctor, D.M. and Relman, D.A. (2017). The Landscape Ecology and Microbiota of the Human Nose, Mouth, and Throat. *Cell Host & Microbe*, 21(4), pp.421–432.
doi:<https://doi.org/10.1016/j.chom.2017.03.011>.
- Ritchie, J. and Lewis, J. (2003). Qualitative Research Practice: a Guide for Social Science Students and Researchers. [online] Google Books. SAGE Publications. Available at: https://books.google.ie/books/about/Qualitative_Research_Practice.html?id=e6EO83ZKGYoC&redir_esc=y [Accessed 21 Apr. 2024].
- Salazar-Gamarra, R., Binasco, S., Seelaus, R. and Dib, L.L. (2022). Present and Future of Extraoral Maxillofacial prosthodontics: Cancer Rehabilitation. *Frontiers in Oral Health*, [online] 3, p.1003430. doi:<https://doi.org/10.3389/froh.2022.1003430>.
- Saunders, M.N.K., Lewis, P. and Thornhill, A. (2012). Research Methods for Business Students. [online] Google Books. Pearson Higher Ed. Available at: https://books.google.ie/books/about/Research_Methods_for_Business_Students.html?id=u4ybBgAAQBAJ&redir_esc=y [Accessed 7 Mar. 2024].
- Sayfeddine Eddous, Guillaume Lamé, Benoît Decante, Yannou, B., Agathon, A., Aubrège, L., Talon, V. and Éléonore Dacosta-Noble (2023). CURRENT AND POTENTIAL APPLICATIONS OF 3D PRINTING IN a GENERAL HOSPITAL. *Proceedings of the Design Society*, 3, pp.1117–1126. doi:<https://doi.org/10.1017/pds.2023.112>.

- Suder, J., Bobovsky, Z., Mlotek, J., Vocetka, M., Zeman, Z. and Safar, M. (2021). EXPERIMENTAL ANALYSIS OF TEMPERATURE RESISTANCE OF 3D PRINTED PLA COMPONENTS. *MM Science Journal*, 2021(1), pp.4322–4327. doi:https://doi.org/10.17973/mmsj.2021_03_2021004.
- Sudhakar, K.N.V. (2017). Evaluation of Donor Site Morbidity Associated with Iliac Crest Bone Harvest in Oral and Maxillofacial, Reconstructive Surgery. *JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH*, 11(6). doi:<https://doi.org/10.7860/jcdr/2017/28688.10053>.
- Sun, Z., Wong, Y.H. and Yeong, C.H. (2023). Patient-Specific 3D-Printed Low-Cost Models in Medical Education and Clinical Practice. *Micromachines*, 14(2), p.464. doi:<https://doi.org/10.3390/mi14020464>.
- Thomas-Seale, L.E.J., Kirkman-Brown, J.C., Attallah, M.M., Espino, D.M. and Shepherd, D.E.T. (2018). The Barriers to the Progression of Additive manufacture: Perspectives from UK Industry. *International Journal of Production Economics*, 198, pp.104–118. doi:<https://doi.org/10.1016/j.ijpe.2018.02.003>.
- Tymms, C., Zorin, D. and Gardner, E.P. (2018). Tactile Perception of the Roughness of 3D-printed Textures. *Journal of Neurophysiology*, 119(3), pp.862–876. doi:<https://doi.org/10.1152/jn.00564.2017>.
- Unkovskiy, A., Spintzyk, S., Beuer, F., Huettig, F., Röhler, A. and Kraemer-Fernandez, P. (2022). Accuracy of Capturing nasal, orbital, and Auricular Defects with extra- and Intraoral Optical Scanners and smartphone: an in Vitro Study. *Journal of Dentistry*, 117, p.103916. doi:<https://doi.org/10.1016/j.jdent.2021.103916>.
- Wei, X., Zou, N., Zeng, L. and Pei, Z. (2022). PolyJet 3D printing: Predicting Color by Multilayer Perceptron Neural Network. *Annals of 3D Printed Medicine*, 5, p.100049. doi:<https://doi.org/10.1016/j.stlm.2022.100049>.
- Wickramasinghe, S., Do, T. and Tran, P. (2020). FDM-Based 3D Printing of Polymer and Associated Composite: a Review on Mechanical Properties, Defects and Treatments. *Polymers*, 12(7), p.1529. doi:<https://doi.org/10.3390/polym12071529>.

- Wong, E., Siu, J., Douglas, R. and Singh, N. (2020). Anatomy and Physiology of the Human Nose. *Biological and Medical Physics, Biomedical Engineering*, pp.9–29.
doi:https://doi.org/10.1007/978-981-15-6716-2_2.
- Yu, T.-H., Su, Y.-H., Huang, H.-H., Tsai, H. and Hsu, W. (2020). Amorphous Fraction Controlled Mechanical and Optical Properties of Polylactic Acid below Glass Transition Temperature. *Polymer Testing*, 91, pp.106731–106731.
doi:<https://doi.org/10.1016/j.polymertesting.2020.106731>.
- Zuniga, J. (2018). 3D Printed Antibacterial Prostheses. *Applied Sciences*, 8(9), p.1651.
doi:<https://doi.org/10.3390/app8091651>.

Appendices

Appendix A:

INTERVIEW CONSENT

I am Kieran Murphy, a Technological University of the Shannon student. I am studying Ireland's current maxillofacial manufacturing value chain to identify best practices for integrating 3D printing into the manufacturing process. You are invited to participate in a research study on the barriers to entry for additive manufacturing. This study aims to understand the experiences and perspectives of individuals who work in additive manufacturing or wish to work in additive manufacturing and identify any barriers to entry they have encountered.

You are employed in a sector the study wishes to target, and we seek to interview participants in Ireland's medical sectors, be it education, consultation, or management. I would like to seek your views. If you agree to participate in this study, you will be asked to do a one-on-one interview. The interview will last approximately 30-45 minutes and will be audio-recorded. You will be asked about your experiences with additive manufacturing and any barriers to entry that you have encountered.

All information collected during this study will be kept confidential. Your name and any identifying information will be kept separate from any data collected during the study. Audio recordings of the interview will be stored securely and only accessible to the research team.

Participation is entirely voluntary, and participants are free to withdraw from the study at any time and may withdraw their data until the work is published.

Please respond to the question below to confirm your participation consent or decline.

Thank you for your participation.

Regards

Kieran Murphy

I agree to participate in this study.

Yes ☐ No ☐

Information: What will happen to the results of this study?

The study results form part of an assessment for the Master of Engineering in Packaging, Innovation and Product Design I am undertaking.

This information will be kept confidential and used solely for the study. Only the researcher and their supervisor will have access to the data collected. The data will be stored securely and destroyed after the study's completion.

Upon completion of the degree programme, all data will be treated following GDPR guidelines.

Researcher's contact details:

Name: Kieran Murphy

Email: Kieran.Murphy@rsgroup.com

Department of Lifelong Learning, Technological University of the Shannon, Athlone Campus

Supervisor name:

e.g. Micheal Fitzpatrick Email: micheal.fitzpatrick@tus.ie

If during your participation in this study, you feel the information and guidelines that you were given have been neglected or disregarded in any way, or if you are unhappy about the process, please contact the supervisor above at the Department of Lifelong Learning, Technological University of the Shannon, Athlone Campus. Please be assured that your concerns will be dealt with sensitively.

Appendix B

Interview questions:

Stakeholder/ Current state:

1. What is the typical referral process for a patient?
2. Please briefly detail the current process map of how patients are referred.
3. What departments are involved?

Manufacturing methods:

1. Can you block out the current methods used to make a prosthetic? For example, impression-taking, casting, etc.
2. How often are the patients required onsite for the manufacturing process?
3. What are the time requirements to finish a single maxillofacial prosthetic?
4. How long does a patient typically wait before receiving the finished product?
5. Do you use any digital tools as part of the manufacturing process? If so, which tools and why?
6. Are you familiar with 3D printing?
7. Are you aware of the applications of 3D Printing?

Materials:

1. How well do the materials hold up with day-to-day usage?
2. When a prosthetic fails, what is the typical point of failure? For example, is it edge strength, discolouring, etc.?
3. How often are prosthetics brought in for maintenance?
4. What is the lifespan of a finished prosthetic?

Additional questions:**Stakeholder/ Current state:**

- How many years have you been working with maxillofacial prosthetics?
- Did you receive your training in the Republic of Ireland? And how long did it take?

Manufacturing methods:

- Can you detail how the dimensions are taken?
- Do you currently use CAD in your manufacturing process?
- How are the prosthetics coloured?
- Would you consider this process difficult?
- How are prosthetics retained on the patient?
- What barriers might prevent the integration of new manufacturing practices?

Materials:

- What type of materials are used?
- What is the industry standard in Ireland?
- What is your preferred material for human tissue emulation?
- How well do the materials used in the prosthetic adapt to facial movements and expressions?
- Do your materials meet your mechanical, aesthetic and functional requirements?
- What limitations have you encountered with working with these materials?
- Does the retention method affect the lifespan?

Appendix C



